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RESEARCH PANEL**

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# Papers Commissioned for the NIH Human Embryo Research Panel

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**Note:** These papers were commissioned in December 1993 to provide background information to the NIH Human Embryo Research Panel.

# **The History, Current Status and Future Direction of Research Involving Human Embryos**

by

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## **Introduction**

The opportunity for experimental research involving early human embryos has become feasible only recently. Coincidentally, the increased clinical utilization of assisted conception technologies such as in vitro fertilization (IVF) for the treatment of infertility and for preimplantation diagnosis of inherited disease provides a source of normal and abnormal human embryos for experimental purposes. With respect to human embryo research, the primary issues addressed in this report can be summarized in the following four questions: (1) what types of research previously have been considered appropriate, (2) what work has already been done, (3) have these investigations resulted in important new information or knowledge, and (4) what future research only can be accomplished with human embryos?

The underlying philosophy that governed the preparation of this document was based on the following premises: (1) because embryos used in experimental studies would most likely be donated by infertile couples and fertile couples carrying known genetic defects, the information obtained from their embryos should have the potential of providing results that could be of direct benefit to these, or to similar individuals, in the near future; (2) for most of the research discussed, comprehensive studies have already been performed in animal systems and the science has evolved to the point where extension to the human is the next logical step; (3) that the described human embryo research will result in fundamentally new information concerning the biological basis of developmental success, failure, normality, and abnormality; (4) that investigations utilizing human embryos have the potential to develop new strategies and treatments for infertility and other diseases. While the scope of this report covers a broad spectrum of human embryo research applications, it is not exhaustive. In this respect, I apologize in advance to those clinicians and research scientists whose interests have not been included.



## **What Types of Human Embryo Research Have Been Considered Necessary and Have Previous Investigations Yielded Important or New Information?**

Up to the present time, most research involving human embryos has been directed to improving the chances of pregnancy in attempts at laboratory assisted conception. The potential uses of human embryos in research unrelated to fertility treatment that have become apparent only recently and are discussed in detail later in this document. However, it should be understood from the outset that human embryo research is not a unique field, but rather one that is derived almost entirely from work with laboratory animals such as the mouse. Virtually all of the present methods used in clinical situations for the preparation of spermatozoa, in vitro insemination of oocytes, and culture and cryopreservation of preimplantation stage embryos have been established in animal systems, and in some cases use procedures and media developed over 25 years ago. It is important to note that in the U.S., nearly all research in animal embryology has been supported by the Federal agencies. The common justification in grant applications that propose to study various aspects of early mammalian development has been that the findings obtained from animal systems will improve our understanding of molecular, cellular, and physiological aspects of early embryogenesis that can ultimately be applied to the human, especially in efforts designed to treat infertility. It is not surprising therefore, that with the nearly universal acceptance of laboratory assisted conception as a treatment of human infertility have come calls from clinicians, research scientists, and the organizations which represent their interests, such as the American Fertility Society, for more active Federal support of research in early human development.

Although there is a clear consensus within the community of infertile couples, clinicians, and scientists involved in medically-assisted conception that more research is needed to increase pregnancy rates, there is no equally strong consensus about what specific types of research will provide the critical findings or definitive results that will truly improve outcome. The question of what studies constitute critical research in human embryology, and which may lead to new clinical treatments for infertility and disease is not a new one. For example, at the Fourth World Congress of In Vitro Fertilization and Embryo Transfer held in Melbourne, Australia in 1985, several session chairman, of which I was one, requested that participants at the meeting submit specific topics, questions, or experiments that they believed necessary to advance the field and improve the chances of an ongoing pregnancy for their patients. I added to this request the following two caveats in order to justify research on human embryos: (1) that the experiments have not already been done, or could not be accomplished in animal systems, and (2) that the findings would be so useful or important that they would fundamentally alter the current methodologies of laboratory assisted conception. Only two studies contained in more than 100 replies were considered appropriate. In order to discover what kinds of investigations with human embryos would be carried out if circumstances permitted, the British journal *Nature* issued "An Appeal to Embryologists" in 1985 to submit research topics and propose experimental studies that could justify the use human embryos. This request was attributed to (1) the absence of a clearly defined statement of what exactly are the benefits of investigations with human embryos, (2) a lack of understanding of what may be meant by research with human embryos, and (3) a dearth of serious proposals for investigations that would make sense. In the United States, the absence of Federal funding for human embryo research in a field of medicine that has experienced enormous growth has been generally assumed to have limited the development of new infertility treatments.

In an effort to define more precisely areas of research in human reproduction that would generate new and fundamental insights into early developmental processes that would be relevant in medically assisted conception, "An Agenda for Research" was produced by the Committee on the

Basic Science Foundations of Medically Assisted Conception, formed in 1988 by the Institute of Medicine of the National Academy of Sciences, and the Board on Agriculture of the National Research Council. This report detailed specific topics that were considered necessary for a more comprehensive understanding of human reproductive biology, and described specific areas of investigation that would have important implications for clinical treatments of infertility. Although the suggested research was based on information available in 1988, most of the scientific questions that were addressed are still relevant or unresolved 6 years later. The summary of the Research Agenda, and the Committee's conclusions and recommendations published by the National Academy of Sciences in 1989 are presented below.

## **Research Agenda**

A workshop was held August 21-23, 1988 at the Arnold and Mabel Beckman Center in Irvine, California. Overviews of the experience gained by the clinical practice of IVFET and of the practice of assisted conception in food-producing animals directed attention to unanswered questions that will require basic science research for their resolution. These questions reflect important gaps in our knowledge of the biology of all the stages of reproduction from the development of male and female gametes to the process of embryo implantation. The topics listed below are areas in which further research was recommended by workshop participants and committee members. Work in these areas is expected to increase understanding of the biology of reproduction with the hope that increased knowledge will eventually lead to improvements in the practice of IVFET in humans and other animals, or to advances in contraception. Research areas are listed here in summary form and apply both to lower animals and human beings unless specifically noted. The complete summary of the workshop is contained in Chapter Two of the full report.

### **Basic Science**

#### **Male Gametogenesis**

- Definition of the role of cell adhesion molecules in interactions between Sertoli cells and developing sperm cells.
- Understanding the function of differential protein synthesis in different stages of sperm development.
- Determination of the role of paracrine factors including fibroblast growth factor, somatomedin C, epidermal growth factor, and interleukin-1 on the development and differentiation of male gametes.
- Structural analysis to identify normal and abnormal sperm and the development of markers for abnormal sperm.
- Understanding of the biochemistry of sperm capacitation.

## **Female Gametogenesis**

- Analysis of the effects of superovulation or hormonal stimulation protocols on oocyte development and maturation. This work should also examine differences between species.
- Development of ways to mature oocytes in vitro.
- Investigation of ways to naturally stimulate oocyte and follicular development.
- Investigation into the biochemistry of meiotic arrest and the factors, such as cyclic AMP, purines, calcium, and maturation-promoting factor, that may mediate this process.
- Development of ways to produce or synthesize hormones from non-human primates to be used in ovarian stimulation.
- Definition of the role of ovarian estrogen in oocyte maturation and ovulation and the interactions between estrogen and paracrine factors including fibroblast and epidermal growth factors, insulin-like growth factor, transforming growth factor, and inhibin.
- Definition of the point at which oocytes become sensitive to factors that influence their development.
- Elucidation of the processes that underlie oocyte depletion, to determine why oocytes are lost at a predictable rate throughout life.
- Investigation into ways to augment natural hormone release.
- Investigation into the biochemistry of protein synthesis and modification in ovarian cells.

## **Fertilization**

- Investigation into the biophysics of cell membranes as it relates to sperm and egg interactions at fertilization.
- Continued investigation to identify the genes for zona proteins in various species, especially humans.
- Further delineation of the role of zona proteins, especially ZP2 and ZP3, in sperm binding.
- Understanding of the biochemistry of the modification of zona proteins in preventing polyspermy.
- Elucidation of the molecular determinants of antibody formation to zona proteins and their possible role in contraceptive strategies.
- Definition of the biochemical mechanisms of the cortical reaction in the egg and the effects of this reaction on zona proteins.
- Determination of the physiological significance of germinal vesicle breakdown and the biochemistry of sperm chromatin decondensation.
- Definition of the molecular events associated with formation of the male and female pronuclei.
- Definition of the molecular events during zygote formation and the first cleavage.

## **Preimplantation Development**

- Definition of the metabolic requirements of early embryos at different stages.
- Determination of embryonic gene expression.
- Assessing the potential of individual embryonic cells and defining the point at which embryonic cells are committed to particular fates.
- Identification of substances produced by early embryos that signal changes in the uterus prior to implantation.
- Improvements in embryo multiplication and embryo splitting, especially for food producing animals.

## **Implantation**

- Definition of the biochemical events that make the uterus permissive to implantation.
- Definition of the factors released by embryos that cause endometrial changes at the site of implantation.
- Identification of the role of embryo-released factors in suppressing the immune responses of the mother.
- Isolation and analysis of substances released by endometrial cells and their effects on embryos.
- Continued work with in vitro models of human implantation to study the biochemistry and mechanisms of embryo-endometrial interactions, especially the role of extracellular matrix proteins and the biochemistry of trophoblast invasion of the endometrium.

## **Technological Advances**

- Improved cryopreservation techniques, including freezing and thawing protocols for eggs and embryos.
- Improved resolution of ultrasonography for localization and noninvasive harvest of oocytes, eggs, embryos—would have particular usefulness for non-human primates and food producing animals.
- Development of new culture media and methods for in vitro maturation of oocytes.
- Development of safe methods of biopsy of early embryos for preimplantation diagnosis of genetic diseases.

## **Clinical Research Opportunities**

The following areas are those in which a coordinated data collection effort across IVFET clinical centers would help improve the quality and success rates of IVFET nationally and, possibly, internationally.

- Evaluation of hormonal stimulation protocols in terms of number of oocytes harvested, quality of oocytes, and rate of fertilization success.

- Documentation on the incidence of abnormal implantation rates in IVFET practice and correlation of incidence with particular stimulation protocol used.
- Collection of information regarding the incidence of abnormal zygotes and embryos, failed fertilization, and developmental arrest of embryos.
- Analysis of data pertaining to synchronization of embryonic stage with endometrial stage and development of methods to improve synchronization.
- Collection of information on sharing of spare eggs and arrested embryos for research purposes.

## **Conclusions and Recommendations**

### **Developing Research Policy**

Lack of a mechanism for dealing with ethical disagreement over the use of embryos in research has slowed the rate of progress in research by, in effect, placing a moratorium on the use of federal funds for eight years. This has had undesirable results: the human clinical practice of IVFET is less effective than it might have been had research progressed at a faster pace; other socially desirable goals such as improved contraception, better techniques to preserve endangered species, and more cost-effective methods of producing food have developed at a pace slower than optimal.

The recent appointment of the Biomedical Advisory Committee by the Biomedical Ethics Board, to report to Congress by November 1990 on embryo research issues, could be a step toward a solution. The committee applauds the intention to revive the Ethics Advisory Board of the Department of Health and Human Services to rule on the ethical acceptability of research relating to human embryos, which is required before federal funding of such a research grant can be considered. However, until these groups become fully functional and show evidence of progress, their impact must remain in question.

If these groups can assume leadership roles in resolving the difficult issues of reproductive research, and develop guidelines for research that are based on information provided by science, and on concepts that are ethically acceptable to society, research in reproduction will be able to move forward. But if these groups become paralyzed because of political considerations or an inability to develop a framework for the resolution of differences of opinion, another organization should take over the role. The committee recommends that, *if the groups currently being formed fail to come to conclusions concerning embryo and fetal research, a non-governmental organization should be established to develop guidelines for embryo and fetal research that are based on the most advanced knowledge that science can muster, and with serious consideration of the expressed values of society. The group should be composed of individuals with expertise in the relevant scientific disciplines, representatives of the lay public, and experts in the legal, ethical, and social issues. The organization should be housed in an institution that would allow it to conduct its deliberations free from any undue pressures from political and special interest groups. A model for such activities can be found in the Voluntary Licensing Authority of Great Britain.*

The scientific and ethical guidelines developed by the Committee in considering questions related to the nature and purpose of research that contemplated the use of human embryos are clearly still applicable. As a member of this Committee, it was evident that an underlying concern of the group expressed during the evaluation of the relative merits of different areas of human embryo research was whether the ends truly justified the means, because more often than not, experimental studies and analyses would require the termination of development. Another concern was whether embryos should be created solely for experimental purposes, or whether appropriate research should be restricted to "spare" embryos donated by patients undergoing in vitro fertilization (IVF). With respect to the use of human embryos, the research topics and experimental studies considered important by the Committee took into account the following "means tests:" Does sufficient evidence from studies in animal models systems (e.g., mouse) and nonhuman primates (e.g., rhesus) exist which can be extrapolated to early human embryos, such that the developmental phenomena or processes under consideration can, with a high level of confidence, also be assumed to occur in the human? This means test asks a fundamental question, namely, does the human experiment need to be done? Two examples of experimental studies which have been the subject of considerable controversy illustrate the extremes of this particular issue.

In 1988, Peter Braude and his co-workers published a study in *Nature* in which human embryos were produced solely for the purpose of determining when uniquely embryonic messenger RNAs (mRNA) were first transcribed from DNA. In general terms, the point of this study was to identify the stage of human embryogenesis when the regulation of development could be assumed to switch from oocyte to embryonic control. A justification for this study was based on the common observation from clinical IVF that more than half of the embryos produced arrested development in culture during the early cleavage stages (4-to-12 cell stage). The important question implicit in this study was whether the etiology of arrested embryogenesis observed in vitro was associated with suboptimal culture conditions, inadequate culture media, or the failure of genomic activation. The detection of newly synthesized proteins presumed to be associated with the transition from oocyte to embryonic developmental regulation might also provide markers that could be used to identify possible causes of arrested development. These workers found that transcription of uniquely embryonic mRNAs occurred around the 6- to 8-cell stage. This study could not provide a definitive answer to the question of whether early developmental failure was related to culture protocols or to developmental problems intrinsic to a particular embryo. However, the results could be considered applicable in clinical IVF because they suggested that the failure of embryos to progress beyond the early cleavage stages may be the result of inherent developmental defects. The controversy surrounding this work centered on two issues. First, ethical objections to the creation of human embryos specifically for experimental research were expressed in numerous letters and opinions published in the scientific literature. Second, it was suggested that the answer to the question of when activation of the human embryonic genome occurred could be inferred both from studies that had already been done in animal systems, and from pioneering light and electron microscopic investigations of human embryos published in the 1960's and early 1970's. However, the importance of the Braude et al study was that it identified for the first time specific proteins associated with human genome activation. Studies of this type would be clinically relevant if some of these new embryonic proteins are secreted and therefore, their presence or absence in culture medium could indicate the normality of early development.

At the 1993 annual meeting of the American Fertility Society, Robert Stillman and Jerry Hall reported "cloning" of human embryos by artificially separating (i.e., twinning) genetically abnormal (triploid) embryos at the 2-cell stage, followed by culture of the individual daughter cells in vitro to the 32-cell stage within an artificial zona pellucida. The basic findings of this study were that

daughter blastomeres could be separated at the 2-cell stage by micromanipulation, and because the resulting twin embryos progressed through the preimplantation stages, developmental fate at the cellular level was not fixed in the very early human embryo (i.e., the cells were totipotent). These investigators suggested that the production of multiple genetically identical embryos could increase the chances for pregnancy through IVF by permitting more embryos to be returned to the infertile patient. It has also been suggested that cryopreservation of excess "cloned" embryos could be used for donation to other infertile couples once the developmental capacity of the transferred sibling embryos had been established.

Many professional scientists in the field of animal and human embryology have argued that ability to isolate and culture through the preimplantation stages the individual cells of very early human embryos was predictable from information already available in the literature. For example, in animal studies, the individual cells of 2- and 4-cell stage embryos have been shown to be capable of normal embryonic development that result in multiple live young (Prather and Robi, 1991). In clinical IVF, normal pregnancies have often occurred from cryopreserved 4-cell embryos in which only 1 or 2 cells survive the thawing process. Removal of a single cell at the 2 or 4 cell stage for preimplantation genetic analysis in the human does not impair subsequent preimplantation developmental, or adversely influence the ability of the embryo to implant and progress through gestation (Handyside, 1994). Artificial "zona pellucidae" of several type have been shown in other species to work effectively in containing the embryo until the blastocyst stage (Willadsen, 1979). On the basis of available information from both the human and animal literature, it has been suggested that the human experiment need not have been performed. As discussed in greater detail later in this document, the clinical application of this line of research, namely the production of multiple identical embryos from the dissociated cells of a single embryo, should be considered premature until noninvasive methods more incisive than gross morphology are developed to assess the developmental potential of each oocyte and embryo.

As noted previously, the goal of most work with human embryos in the U.S. has been to increase the frequency of pregnancy associated with laboratory-assisted conception. In this sense, the types of investigations that have used human embryos can be categorized as (1) traditional embryological research, which seeks to describe and understand underlying biological principals and processes, and (2) attempts to modify laboratory techniques and clinical protocols used for in vitro fertilization. To date, the vast majority of published studies from U.S. programs has been of the latter type. Traditional research involving molecular and cellular biological studies of human embryos has come from primarily from European and Australian IVF programs, especially those in which professional scientists are engaged in both research and clinical activities. This is in contrast to the situation that prevails at most U.S. programs where Ph.D. level scientists function primarily as directors of IVF laboratories.

Because the distinction between technique/protocol and basic research in human reproduction is often obscure, especially to nonscientists, the following narrative describes separately the work done in these areas. This section also discusses the extent to which these studies have contributed to our current understanding of early human development, and whether such studies have ultimately been of benefit to infertility patients.

## **The Contribution of Human Embryo Research to the Development of Laboratory Techniques and Clinical Protocols Used in the Treatment of Infertility**

Most of the current methods used in laboratory-based treatments of human infertility have evolved from those used to produce the first successful human pregnancy by in vitro fertilization. This now universally accepted procedure was first performed by Drs. Edwards and Steptoe in 1978 in the U.K. However, even this success was not unexpected because it represented a logical application of previous experimental findings (cited below) which demonstrated that human oocytes could be fertilized in culture, and that the resulting embryos were capable of progressing through the early preimplantation stages in an apparently normal manner. In this respect, contemporary discussions and evaluations concerning the relative merits of human embryo research should note the extent to which the current enterprise of clinical IVF owes its existence to the pioneering studies of Rock and Menkin (1944), Edwards et al (1969), and Soupart and Strong (1974). It was this early research in human embryology, which in its time was also quite controversial, that established the basic science foundation of clinical IVF. Since 1978, hundreds of thousands of cycles of laboratory-assisted conception have been undertaken at specialized infertility centers throughout the world. The proliferation of clinical IVF programs is especially marked in the United States where, according to recent surveys by the American Fertility Society, over 250 centers have treated tens of thousands of infertile couples. In the context of the current debate over what are the exact benefits of investigations with human embryos, perhaps the most obvious benefit to come from the original studies cited above is the acceptance of in vitro fertilization as a primary treatment for infertility and the many thousands of children whose existence is a direct result of this work.

### **Human Embryo Research Directed at Improving IVF Outcome—Nature versus Nurture**

The relatively low pregnancy rates observed in many IVF centers during the mid 1980's, coupled with consistent reports of apparently aberrant patterns of embryonic development in vitro were widely thought to be a consequence of suboptimal media or culture conditions. Indeed, most of the media formulations and laboratory methods used for human embryo culture were derived from cell culture and embryological research dating back to the 1960's, if not somewhat earlier. In order to circumvent presumed nutritional and environmental deficiencies, attempts were made to formulate culture medium and conditions that more closely approximated the chemical environment provided for the embryo within the reproductive tract. A variety of supplements, including maternal serum, human umbilical cord serum, amniotic fluid, human serum albumin, bovine serum albumin, growth factors, and others reagents were introduced (reviewed by Van Blerkom, 1991, 1994a), and while some of reports indicated significant improvements in the overall appearance of cultured embryos, and increased pregnancy rates, other studies showed little significant improvement either in gross morphology or pregnancy outcome, and some demonstrated the specific supplements actually had adverse influences on human embryonic development. While a substantial literature of human embryo culture has emerged during the last decade, this enterprise has not contributed significantly to our understanding of what special or unique conditions may be required to maximize the developmental ability and potential of cultured human embryos. This is not to say that progress in this area has not been made. A relatively few, well-designed and controlled studies have indicated changes in medium composition that may indeed better support preimplantation human development in vitro (Bavister, 1992).



The very recent introduction of co-culture systems in clinical IVF, which involves incubation of embryos in the presence of a cellular monolayer, has been suggested to improve the normality of preimplantation embryogenesis and increase the probability that a pregnancy after embryo transfer. The rationale for embryo co-culture is based on the following assumptions: (1) current formulations of synthetic culture medium, including those designed to approximate human tubal biochemistry, even with the addition of complex supplements and growth factors, are suboptimal for human embryogenesis; (2) a cellular monolayer may provide biochemical and biophysical conditions similar to those encountered by the preimplantation stage embryo in the oviduct or uterus; (3) "embryotropic" factors which promote a more normal pattern of preimplantation embryogenesis in vitro may be secreted by the cultured cells; (4) co-culture may detoxify medium by removing heavy metal cations, or metabolic inhibitors, or both. Cells in current use for human embryo co-culture have been derived from a wide variety of human (e.g., uterine and tubal epithelia, follicular granulosa cells), animal (e.g., bovine uterine and tubal epithelia, fetal bovine fibroblasts), and established cell lines (e.g., Vero). However, the indication that a superior pattern of human preimplantation development occurs during co-culture with cells of different tissue and species origins suggests that the putative beneficial influences for embryogenesis are not specific to the human reproductive tract.

Although co-culture has been rapidly incorporated in clinical IVF, whether it is actually improves embryonic development and pregnancy outcome is questionable (Bavister, 1992,1993; Bongso, 1993; Plachot et al, 1993; Van Blerkom, 1993). Most recently, co-culture has been combined with "assisted hatching," a technique that involves the chemical dissociation of a portion of the zona pellucida during the early cleavage stages. The zona pellucida is an acellular coat that forms around the oocyte during oogenesis, is a barrier to polyspermic penetration at fertilization, and has the ability to isolate the embryo from potentially harmful agents or influences during the preimplantation stages. The emergence of the embryo from the zona pellucida at the blastocyst stage is a prerequisite for implantation. The technique of assisted hatching in clinical IVF has been suggested to increase the probability of embryo emergence from the zona pellucida and therefore, the likelihood of implantation after embryo transfer (Cohen, 1992).

With respect to improved embryonic development in vitro and increased pregnancy rates after embryo transfer, the relative merits of co-culture and assisted hatching, either individually or in combination, have yet to be determined unambiguously. In addition, several investigators have expressed concerns about the wisdom of exposing human embryos with rents in the zona pellucida to cellular monolayers derived from slaughterhouse material or human surgical specimens, especially when potent growth factors have been included in the culture medium (Bavister, 1992; Van Blerkom, 1993). In recent critiques and debates concerning co-culture utilization in clinical IVF, Barry Bavister (1992,1993) has argued that this line of investigation detracts from more fundamental research that addresses the physiological, nutritional, and metabolic requirements of the preimplantation-stage human embryo. Research directed at understanding these aspects of early human embryogenesis could provide (1) objective criteria and clinically applicable, noninvasive methods to assess the normality of development (some of which are described later in this report), and (2) results that can be used to derive a standard, defined culture medium for the support of fertilization and human embryonic development in vitro. Alternatively, Bongso et al (1993) have argued that co-culture research should lead to the detection of conditions or biochemical factors that are developmentally beneficial and once identified, could be included in the formulation of synthetic human embryo culture medium.

The analytical approach taken by most IVF programs to the assessment of human embryonic development in vitro is empirical rather than quantitative, i.e., does a particular change in medium

composition result in better “looking” embryos. Unfortunately, many studies have shown that gross morphology is rather a poor indicator or predictor of the developmental potential of human embryos (for review, see Van Blerkom, 1991). From personal knowledge and experience in human IVF, it is my belief that most clinicians and laboratory personnel in this field recognize only factors extrinsic to the oocyte and embryo as causes of fertilization and developmental failure. This attitude tends to redirect responsibility for IVF failure away from the inherent biology of gametes and embryos and towards such issues as the quality of water, purity of reagents, and composition of culture medium. Although attention to detail in all aspects of human embryo production is essential in clinical IVF, basic research investigations of early human development indicate that intrinsic biological factors are equal, if not greater influences on the viability of gametes and the developmental ability of the early embryo.

A view of human development that has influenced much of the clinical research in reproductive medicine is that oocytes produced by an optimized endocrine protocol should be generally equivalent in developmental potential, and after fertilization, if given an appropriate culture, tubal, or uterine environment, should be capable of developing progressively. This nurture-dependent view of early human development underlies the use of co-culture in the 1990's, and contributed significantly to the introduction of GIFT (gamete intrafallopian tube transfer) and ZIFT (zygote intrafallopian tube transfer) as treatments for infertility in the mid 1980's. In the GIFT procedure, sperm and oocytes are deposited directly into the fallopian tubes at the approximate region where fertilization would normally occur. A significant drawback to this procedure is that in the absence of a pregnancy, a determination of whether fertilization actually occurred cannot be made. The ZIFT procedure involves insemination of oocytes in vitro and transfer of newly fertilized, 1-cell eggs to the ampullary region of the fallopian tube(s). In contrast to IVF-UT (uterine transfer), both ZIFT and GIFT required laparoscopic surgery.

Another important reason why GIFT and ZIFT had received such widespread and immediate clinical acceptance was based on the notion that a primary cause of low pregnancy rates after embryo transfer was a lethal asynchrony between the developmental stage of the embryo and physiological state of the uterine epithelium at the time of transfer. According to this interpretation, protocols of ovarian hyperstimulation used in clinical IVF-UT to induce the growth of multiple follicles could have the unintended consequence of creating a physical or biochemical milieu that cannot support embryogenesis or is inconsistent with implantation. The conclusion that a “uterine” factor was a proximate cause of pregnancy failure after IVF-UT was supported by numerous reports that attempted to correlate outcome from ZIFT and IVF-UT cycles with endocrine parameters (e.g, serum progesterone and estrogen levels) and ultrasonographic measurements of endometrial thickness. Therefore, replacement of fertilized eggs at the 1-cell stage in infertile women with patent fallopian tubes was considered to provide both a more physiologically appropriate environment for early development, and allow embryos to enter the uterus at a time when the state of uterine development was more favorable for implantation. Indeed, in comparison to conventional IVF-UT, many studies reported improved pregnancy rates after GIFT or ZIFT in cases with significant male factor involvement, or where advanced maternal age could be considered a contributing factor to infertility.

As discussed by Van Blerkom (1994a), the evolution of reproductive medicine during the last decade has been marked by the temptation to alter basic laboratory methodology or adopt new clinical procedures that have been suggested in initial reports to improve pregnancy outcome. Many of the studies that indicate improved patterns of embryo development or higher rates of pregnancy often lack adequate controls, describe findings obtained from a small or select patient population, or both. Consequently, the findings and interpretations may not have the full weight of statistical significance

that can only be derived from well-designed, prospective randomized trials. Such findings usually provide the justification for fundamental change in clinical or laboratory procedures, especially when associated with increased patient risk or cost.

Unfortunately, the imperative to offer patients a higher probability of success can result in the adoption of new procedures before their actual merits and specific applications have been fully established. This situation has been particularly evident in the field of medically assisted conception. For example, many published reports described substantial increases in pregnancy outcome with ZIFT as compared to conventional IVF-UT performed at the same program (see Van Blerkom, 1994a for review). However, few of these studies either noted or could explain why their observed IVF-UT rates were often significantly lower than those reported by other programs in which IVF-UT was used to treat the same spectrum of infertility and included patients stimulated according to identical endocrine protocols. Several recent reports have summarized the pregnancy outcomes resulting from IVF-UT and ZIFT performed at the same program over several years, or have described findings from prospective, randomized trials designed to include large numbers of patients of similar ages and fertility histories (both male and female). These studies have failed to demonstrate a statistically significant difference in ongoing pregnancy rates after ZIFT or IVF-UT (Toth et al, 1992; Tournaye et al, 1992). With respect to earlier claims that pregnancy rates in male factor cases were improved significantly by ZIFT, more recent studies that have been both better controlled and prospective in design have found no advantage to ZIFT in male factor infertility, or in cases involving oocyte and embryo donation (Pados et al, 1992; Tournaye, et al, 1992). While these findings do not exclude the possibility that ZIFT may be the procedure of choice for some patients, it is not the breakthrough that had been suggested when first introduced. Indeed, these results have led several clinical investigators to conclude that the quality (i.e. nature) of the gametes and the resulting embryos is probably the most significant factor associated with success for failure in assisted conception (Acosta, et al, 1988; Ezra et al, 1992; Navot et al, 1991; Toth et al, 1992).

The above findings illustrate the importance of obtaining statistically significant results that are derived from well-designed, prospective, randomized trials. Such results are clearly required in order to justify fundamental changes in clinical protocols that may be associated with added risks and costs to patients, as is frequently the situation with the ZIFT procedure (Pool et al, 1990). As discussed by Van Blerkom (1994a), there has been a tendency in the field of clinical IVF to incorporate "new" laboratory methods or adopt clinical protocols based solely on published results that ordinarily would be interpreted with caution or considered preliminary because of insufficient patient numbers, inadequate experimental design, or both. The notion that a particular laboratory method or clinical protocol will make a fundamental difference in pregnancy outcome that is applicable to very different etiologies of infertility reflects a common perception about human embryology that seems to pervade the field of assisted conception. It is in this sense that the "nurture" side of embryonic development has been a common theme of clinically-oriented research involving human embryos during the last 15 years. Whether our knowledge and understanding of human embryogenesis has advanced in proportion to the voluminous literature that has been generated is debatable. This statement is not intended to diminish the very considerable efforts of many research and clinical scientists who have made significant contributions to infertility treatment. However, a fact that still needs to be contended with is that most human embryos, whether conceived in vivo or in vitro, will not develop into viable pregnancies (Edwards, 1986; Osborn and Moor, 1989; Burgoyne et al, 1991; Jacobs, 1992).

Coincident with the evolution of the field of human reproductive medicine has come the realization that continued advances in infertility treatment will require a more comprehensive

understanding of the molecular and cellular biology of human embryogenesis and implantation than currently exists, and the ability to translate this understanding into clinically detectable markers or indicators of developmental potential and viability. Consequently, the following narrative is devoted to the “nature” side of human embryo research.

## **The Current Status and Clinical Applications of Human Embryo Research That Address Biological Aspects of Embryogenesis**

While it may be reasonably argued that the absence funding and restricted or limited availability of research material are the principal reasons why basic research in human embryology has not progressed rapidly, it is equally true that clinical IVF has not been a field that has attracted the high caliber of trained research scientists common to other areas of developmental biology. Consequently, although many Ph.D.-level scientists are involved in IVF programs, clinical laboratories are not necessarily designed to support an active and significant research component. The major advances in our understanding of human gametogenesis and embryogenesis during the last decade have come predominantly from the efforts of basic scientists who were trained as embryologists or developmental biologists. A primary objective of human embryo research is to advance our ability to recognize critical events and processes associated with normal and abnormal human development. It is my belief that this goal will be achieved more rapidly if research support is directed to investigations of those fundamental aspects of human development that will attract imaginative scientists who can apply modern concepts and methods in molecular and cellular biology to human embryo research.

## **Intrinsic Factors That Influence the Developmental Potential and Normality of Human Embryos**

The cumulative worldwide findings from over 15 years of experience with clinical IVF and related procedures has clearly shown that an astonishingly high frequency of developmental failure occurs during human embryogenesis (Edwards, 1986; Burgoyne et al, 1991). A primary cause of early embryonic failure observed with medically assisted conception has been thought to be associated with abnormal steroid (e.g., progesterone, estrogen) and gonadotropic hormone (e.g., luteinizing hormone, follicle stimulating hormone) levels that accompany ovarian hyperstimulation. The consequence of an inappropriate balance or level of these hormones has been suggested to result in the generation of a follicular, tubal, or uterine environment that compromises the fertilizability of the oocyte, or the capacity of the embryo to develop and implant (Albrecht, 1994). This notion has led to the search for optimal protocols of ovarian stimulation and hormone levels that produce higher frequencies of pregnancy.

Although a truly enormous number of clinical studies has been published over the last 10 years, there is no actual consensus as to whether one protocol of ovarian stimulation is more successful than another, or whether different frequencies of embryonic development in vitro and ongoing pregnancy after oocyte (GIFT) or embryo transfer (ZIFT, IVF-UT) are associated definitively with a specific endocrine profile (Albrecht, 1994). However, what some of the more well-designed studies have shown is that for women with specific etiologies of infertility, one approach to ovarian stimulation may be more effective than another. The ambiguity associated with this line of clinical investigation, as well as the not infrequent occurrence of studies in the reproductive endocrine literature that arrive at very different or opposite conclusions, has led to a

critical reappraisal of the influence of endocrine factors on the success or failure of early human development. Indeed, some clinical studies have recently suggested that (1) measurements of gonadotropin and steroid hormone levels may not be helpful as previously supposed in predicting outcome in attempts at laboratory-assisted conception (Steinkampf et al, 1992), and (2) that the probability of pregnancy in women with normal ovulatory function and similar etiologies of infertility that require IVF-UT appears to be equivalent in unstimulated (i.e, natural menstrual cycle) and hormonally stimulated cycles (i.e. exogenously managed or artificial menstrual cycle) (Paulson et al, 1992).

As noted above, a growing body of clinical findings and experimental analyses indicates that the success or failure of early human development is highly dependent upon embryo quality. What is not so clear is what extrinsic and intrinsic influences determine quality in general, and for infertility treatment in particular, what clinically identifiable characteristics are associated with developmental potential. However, basic research studies of human oocytes and preimplantation stage embryos have provided critical insights into intrinsic factors that are proximate determinants of developmental normality and potential. One of the more important results to come from these studies is the finding that human oocytes are developmentally heterogeneous and that most, even if fertilized, will not result in a viable pregnancy. This conclusion is very clearly indicated by the multiyear pregnancy outcome data reported by numerous infertility programs to European and U.S. agencies (ILA, 1992; MRI, 1992; SART, 1993). For example, up to the present time, considerably less than 5% of the hundreds of thousands of oocytes used in IVF, ZIFT, or GIFT procedures have resulted in ongoing pregnancies. The following section describes research with human oocytes and embryos that has only recently identified some of the most important and common causes of this exceptionally high degree of failure.

## **Genetic Abnormalities**

The most significant cause of developmental failure in human reproduction appears to be a high frequency of abnormalities in chromosome number (aneuploidy) or structure, or both, that occur in the oocyte during preovulatory maturation (Jacobs, 1992; Van Blerkom, 1994a, for reviews). While the presence of such abnormalities does not necessarily preclude fertilization or prevent the embryo from undergoing the earliest stages of embryogenesis (Munne et al, 1993), many chromosomal anomalies observed in human oocytes and preimplantation-stage embryos would be expected to be developmentally lethal. It has been estimated that on average, approximately 25% of all potentially fertilizable human oocytes are aneuploid (Van Blerkom, 1994b). However, several investigators have shown that for some women, all or nearly all of the oocytes produced during attempts at laboratory assisted conception are chromosomally abnormal. This finding suggests that a predisposition to aneuploidy may be an unrecognized or undiagnosed cause of infertility (Zenzes et al, 1992). At present, it appears that a major fraction of the chromosomal abnormalities detected in pre- and postimplantation human embryos originate in the oocyte and therefore preexist fertilization (Burgoyne et al, 1991; Jacobs, 1992; Van Blerkom, 1994b).

With respect to the theme of "nature versus nurture" in human embryo research, cytogenetic findings indicate that modifications of culture medium and other extrinsic influences cannot rescue from failure the seemingly significant proportion of embryos whose developmental ability is already determined prior to fertilization. This is not to say that basic research applied to improving culture media and conditions should not be encouraged and supported. Such research should provide a better understanding of the nutritional requirements of the preimplantation stage human embryo and result in the derivation of optimized media and conditions for embryo culture in general, and clinical IVF in

particular. Indeed, rapid progress in understanding the biology of early human embryogenesis will require that research efforts focus simultaneously on the identification of extrinsic factors that may influence the progression of development in vitro, and on the recognition of intrinsic factors that determine developmental normality.

## **Abnormalities in Cell Structure, Embryonic Organization, and Biochemistry**

Findings from cellular, molecular, and physiological studies of mature (i.e., potentially fertilizable) oocytes support the notion that human oocytes and preimplantation stage embryos are developmentally heterogeneous. Many IVF laboratories attempt to predict developmental potential during the early cleavage stages by morphological assessments of cytoplasmic appearance, cellular geometry, rate of cell division, and the presence or absence of cytoplasmic fragments (Van Blerkom, 1991, for review). Unfortunately, all of these schemes are subjective and the determination of what grossly observable characteristics are associated unambiguously with developmental outcome can vary significantly among clinical embryologists. None of the current systems for embryo grading are truly predictive of outcome. This conclusion is illustrated daily in clinical IVF by (1) the very frequent failure of cleavage stage embryos classified as “high grade” or “textbook” in appearance to progress in culture or implant after uterine transfer (Van Blerkom 1993, Plachot et al, 1993; Dokras et al, 1993), and (2) by the comparatively less frequent occurrence of pregnancies resulting from embryos classified as poor or very low grade owing to irregular cell divisions or numerous cytoplasmic fragments (Bolton et al, 1989; Puissant and Leroy, 1989; Van Blerkom, 1991). Research directed at computerized image analysis of preimplantation stage human embryos may provide more definitive, objective criteria for assessment of viability and developmental potential.

Development to the expanded blastocyst stage has been suggested to indicate both a normal progression of preimplantation embryogenesis and a high potential for continued development after uterine transfer. Some investigators have proposed that replacement of human embryos at the blastocyst stage should be associated with higher frequencies of pregnancy because developmentally compromised embryos usually fail to reach this stage of embryogenesis. However, recent findings suggest that development to the blastocyst stage is not necessarily a reliable indicator of subsequent developmental potential. For example, several studies have shown that human blastocysts frequently contain (1) too few cells to be developmentally viable (Winston et al, 1991; Van Blerkom, 1993), and (2) an inner cell mass (the portion of the preimplantation stage embryo from which the embryo proper (fetus) develops) that is abnormal with respect to cell number or organization (Hardy et al, 1989).

Human embryo research that has identified abnormalities in inner cell mass formation provides a possible early developmental cause of anembryonic pregnancies (so-called “blighted ovum”), a situation that is very common in both natural and assisted conceptions. These pregnancies are characterized by a normal and progressive rise in the level of human chorionic gonadotropin (hCG) during the first few weeks post conception (termed a chemical pregnancy), but no ultrasonographically detectable fetal pole or heartbeat (termed a clinical pregnancy) by the 5th week post embryo transfer in IVF, or by the 7th week post LMP (last menstrual period) in a natural conception. The occurrence of anembryonic pregnancies is a further example of developmental heterogeneity and failure associated with the earliest differentiative stages of human embryogenesis. Consequently, important current areas of human embryo research are the identification of mechanisms involved in blastomere allocation between the inner cell mass and trophectoderm during the preimplantation stages, and elucidation of the molecular and genetic process that commit blastomeres to very different differentiative pathways and fates.

In addition to developmental heterogeneity that has a genetic basis, very significant differences at the metabolic (Leese et al, 1986; 1993; Magnusson et al, 1986) and molecular levels (Tesarik, 1994) have been observed in the same cohorts of oocytes and early embryos produced by both fertile and infertile women. For some infertile women, most or all of the oocytes and embryos produced in IVF attempts may have an inherent metabolic inability to support development beyond the first few cell divisions (Van Blerkom and Davis, 1994). Metabolic insufficiency may also be a proximate cause of the exceptionally high rate of developmental failure observed with increasing maternal age. Abnormalities or pathologies in cell structure and organization associated with fertilization failure and an arrest of development during cleavage have also been reported to occur at relatively high frequency in human oocytes (for review, Van Blerkom, 1994b), and for some infertile women, are observed repeatedly in attempts at in vitro fertilization. Van Blerkom and Henry (1992) described specific types of cellular disorders detectable in living oocytes that were highly correlated with genetic anomalies, fertilization failure, and early developmental arrest (Van Blerkom, 1994b). Although experimental studies of human embryos are comparatively few in number, and in some cases the results are of a preliminary nature, the findings do support the general notion that genetic and developmental processes which occur in the oocyte prior to insemination contribute significantly to fertilizability, and to some yet unknown extent, may determine the developmental potential of the embryo.

An understanding of the developmental program of early human embryogenesis will require research directed at elucidating the patterns and regulatory mechanisms involved in gene expression and cellular differentiation during the preimplantation stages. The importance of such an understanding would be demonstrated by the ability to recognize deviations in this program in unfertilized oocytes, and in embryos that either arrest development or display aberrant patterns of development. Although unfertilized oocytes and presumed abnormal embryos are usually discarded in most IVF programs, they represent a significant source of experimental material which could provide new insights into the molecular and cellular basis of reproductive success or failure.

## **Embryo-Derived Pregnancy Signals and Growth Factors**

A surprisingly large number of molecular factors are secreted by preimplantation stage human embryos, and their stage-specific expression appears to be essential for the progression of embryogenesis, implantation, and embryo survival after implantation. These secreted molecules can be detected in culture medium by noninvasive methods and for some, their presence or absence has been correlated both retrospectively and prospectively with pregnancy outcome (Ryan and O'Neill, 1994). In general, many of these factors are signals that are presumed to be involved in the maternal recognition of pregnancy. For example, platelet activating factor (PAF) and early pregnancy factor (EPF), which have been detected in culture medium containing newly fertilized eggs and early cleavage stage embryos, respectively, may be responsible for an early and local immunosuppression within the reproductive tract. The synthesis and secretion of these two factors has been suggested to be associated with embryonic viability and pregnancy potential in the human (Ryan and O'Neill, 1994).

In addition to PAF and EPF, transforming growth factor, alpha-interferon, tumor necrosis factor, insulin-like growth factor II, epidermal growth factor, prostaglandin E2, and interleukin-1 are secreted by human embryos during specific stages of preimplantation embryogenesis. Some of these factors are thought to promote the morula-to-blastocyst transition, while others have been proposed to act on the reproductive tract to stimulate cell division, effect a local immunoprotection of the embryo,

or promote cell surface changes in the uterine epithelium required for implantation (Lopata and Hay, 1994; Ryan and O'Neill, 1994, for reviews). In preparation for implantation, human blastocysts synthesize laminin and express cell surface receptor proteins (beta-1-integrins) that enable attachment to the extracellular matrix of the uterine epithelium, and produce type IV collagenase activity that facilitates the invasion of the embryonic trophoblast into the endometrium.

Chorionic gonadotropin (hCG) is the best described and most extensively studied signaling glycoprotein produced by the human embryo. Although hCG is secreted specifically by trophoctodermal cells at the blastocyst stage, the mRNA which encodes the hCG molecule is transcribed as early as the 6- to 8-cell, well before any morphological differentiation between trophoctoderm and inner cell mass occurs. hCG is essential for embryo survival and the establishment of early pregnancy because one of its primary functions is to promote and maintain progesterone synthesis by the corpus luteum, the endocrine organ that develops from the residual ovulated follicle. Because hCG can be measured in maternal serum as early as day 7 post-conception, and in maternal urine some days later, it is this molecule (beta subunit) that forms the basis for early pregnancy detection assays. The level of hCG in blood rises progressively and rapidly to peak at 9 to 11 weeks of gestation. The amount of hCG and the rate at which it rises are associated with, if not highly predictive of, the normality of early gestation. A slow rise and low level of hCG can indicate a failing pregnancy, or of greater significance to the health of the mother, the possibility of a tubal (ectopic) pregnancy. An unusually rapid increase and exceptionally high levels of hCG can indicate the occurrence of an abnormal pregnancy, such as a molar pregnancy (hydatidiform mole), which can result from penetration of the oocyte by two sperm (triploid embryo). In addition to its direct action on the corpus luteum, hCG has been implicated in the modulation of the uterine cellular immune response (Yagel et al, 1989), and the process of attachment and adhesion of the embryo to the endometrial epithelium during implantation (Lopata and Hay, 1994).

The identification of embryo-derived growth factors and signal molecules, the elucidation of the molecular mechanisms involved in their expression, and their role in early development are some the most exciting areas of research in human reproductive biology. Based on the increasing awareness of the role of growth factors in cell, tissue, and organ function, discoveries from other fields of medical research (e.g., stem cell and tumor biology) will clearly be relevant to questions of human development (Waterfield, 1990). Because human implantation is an invasive process associated with localized immunosuppression and rapid cell growth and proliferation, the characterization of embryo-derived growth factors could provide new insight into the molecular and cellular biology of tumor formation and metastatic processes. This type of human embryo research will not only increase our basic understanding of the molecular genetic regulation of development, but will also attract to the field of reproductive biology talented clinical and basic research scientists. The relevance of these investigations in reproductive medicine would be demonstrated by the introduction into the IVF laboratory of noninvasive, quantitative assays that can detect, for each oocyte or embryo, secreted molecules identified as important markers of developmental normality and potential.

## **Clinical Applications of Human Embryo Research Other Than in the Treatment of Infertility**

### **Preimplantation Genetic Diagnosis**

Preimplantation genetic diagnosis is perhaps the best current example of how the principles and methodologies of molecular biology can be applied to human reproductive medicine. The



detection of specific genetic disorders and defects in very early cleavage stage human embryos derives from the convergence of the following four technologies: (1) isolation of single cells or clusters of cells from preimplantation stage embryos without adversely affecting subsequent development, (2) amplification of chromosomal DNA from a single cell by polymerase chain reaction (PCR), (3) detection of specific nucleotide sequences on specific chromosomes in single embryonic cells by fluorescent in situ-hybridization (Sawyer et al, 1992), and (4) embryo cryopreservation with reasonably high rates of survival and retention of developmental potential. Currently, several clinical IVF centers in the United States and Europe offer preimplantation genetic diagnosis for couples with familial histories of specific genetic defects and inherited diseases (Handyside, 1994). Virtually all of the methods in current clinical use were examined, refined, and tested in traditional animal systems (e.g, mouse) before human application was considered appropriate.

At present, molecular probes for both sex (X,Y) and autosomal chromosomes have been applied in human preimplantation genetic diagnosis. Sex identification for X-linked recessive diseases is one of the most potent applications of this methodology because nearly 300 X-linked recessive conditions have been described for the human, including Duchenne muscular dystrophy and X-linked mental retardation associated with the fragile X syndrome (Handyside, 1994). Lesch-Nyhan syndrome only affects males and results from a deficiency of the X-linked enzyme hypoxanthine guanine phosphoribosyl transferase. Molecular analysis of single cells isolated from early preimplantation stage human embryos has successfully detected the presence of the altered gene in male embryos (Handyside, 1994). As noted by this investigator, the majority of X- or Y-linked diseases can be prevented simply by identifying embryonic sex and transferring only female or male embryos, respectively. For diseases associated with autosomal chromosomes, a mutation associated with cystic fibrosis has been used to identify affected human embryos (Handyside et al, 1992).

Findings from the American Human Genome Project and its European and Asian counterparts have already contributed significantly to our understanding of the genetic basis of disease. Ultimately, mapping of the human genome will identify genetic defects associated with abnormal embryonic and fetal development. The application of molecular probes generated by this enterprise to preimplantation diagnosis will change profoundly the current practice of reproductive medicine in general, and reproductive genetics in particular. The merging of these two disciplines, which has already occurred at some U.S. centers, involves the extension of IVF methodology to fertile couples. The application of IVF and preimplantation diagnosis where genetic disorders are indicated by familial histories is an inevitable consequence of the convergence of human molecular genetics and human reproductive medicine. Ethical considerations notwithstanding, the combination of these technologies offers in the immediate future the ability to identify embryos with lethal or life-threatening genetic defects. This will become especially evident as the list of molecular probes available for genetic diagnosis expands. With this in mind, genetic research with human embryos in the immediate future might seek to (1) improve the sensitivity and accuracy of genetic defect detection, and (2) refine current invasive methods or develop noninvasive strategies for embryo analysis.

## **Genomic Imprinting**

The finding that laws of classical Mendelian genetics cannot explain the differential expression of specific genes during mammalian embryogenesis, and the expression of certain recessive gene defects in the adult organism, is one of the most important discoveries in mammalian developmental biology to date. In general, the genetic basis of this phenomenon is the differential biochemical

modification (methylation) of specific regions of maternally- and paternally-derived DNA at the 1-cell stage of embryogenesis. Some genomic imprinting may also occur during gametogenesis of the sperm and oocyte, and in adult cells as well. For the newly penetrated egg, however, this differential modification of DNA results in structural differences between the maternally and paternally inherited genomes. These differences are associated with the expression or silencing of a gene on one of the parental chromosomes. The term genomic imprinting has been used to describe this developmentally significant process because the pattern of expression of certain genes is established at the earliest stage of embryogenesis and can persist throughout adult life. De-Groot and Hochberg (1993) defined the term genomic imprinting to refer to any uniparental-dependent transmittance of a genetic trait. Genomic imprinting explains the etiology and pattern of expression of specific human pathologies and genetic disorders associated with mutated or deleted nucleotide sequences involving only one parental chromosome (Solter, 1988). Genetic imprinting has also been suggested to be involved in the origins of certain human cancers (Sapienza, 1991; Scrable et al, 1990), including chronic myeloid leukemia (Silva et al, 1991).

Genomic imprinting plays a fundamental role in mammalian development. Work with experimentally manipulated mouse embryos (Surani, 1991), and findings from human tissues of genetically abnormal pregnancies (e.g., complete and partial hydatidiform mole) and ovarian teratomas (De-Groot and Hochberg, 1993, for review) indicate that placentation is regulated largely by imprinted genes of paternal origin, while development of the embryo proper is regulated by imprinted genes of predominantly maternal origin. Whether genomic imprinting is involved in the regulation of differentiation in the early mammalian embryo is unknown. However, the identification of such genes in model systems would be of immediate relevance to the human because it would provide a powerful molecular genetic approach for investigations into the causes of developmental failure during the preimplantation and postimplantation stages. As noted by De-Groot and Hochberg (1993), research in genetic imprinting is only in its infancy; although a very limited number of genes have proved to be imprinted, many others are suspected. While it may be premature to initiate the search for imprinted and nonimprinted genes in normal human embryos, research utilizing embryos that develop after dispermic fertilization should be encouraged because these genetically abnormal embryos (triploids) may serve to identify specific imprinted genes involved in the formation of the extraembryonic structures that develop into the placenta.

## **Culture of Embryos Beyond the Preimplantation Stages**

A variable degree of development beyond the preimplantation stages has been obtained in vitro with the blastocyst stage embryos of several mammalian species. The application of this line of investigation to the human embryo could have profound implications in our understanding of maternal influences on development, the differentiation of extraembryonic membranes, the origin and differentiation of cell lineages that form the embryo proper, and immunological aspects of early gestation. The development of culture systems that promote postimplantation human embryogenesis may also provide a mechanism for teratogen testing, the introduction of genetic modifications into the germ-line (Wivel and Walters, 1993) and as described below, the generation of stem cells. Although very little work in this area has been reported for the human (Lindenberg and Hytell, 1989), human embryo culture beyond the preimplantation stages is permitted in some countries (e.g., U.K.). Ethical issues notwithstanding, owing to the potential applications of postimplantation culture, serious consideration should be given to the support of this research.

## Applications of Human Embryos in Stem Cell Research

Recent advances in the derivation of cell lines from in vivo and in vitro developed post-implantation mouse embryos have shed light on a potentially important new use of human embryos and embryonic tissues. Stem cells are those cells that serve to renew tissue throughout life. It has become the common use of the term "stem cell" to refer to those cells within the adult organism which provide tissue renewal, but the most fundamental stem cells are those which establish the particular tissue during embryonic development. Recently, several groups have attempted to determine if these fundamental embryonic stem cells can serve to reestablish tissue within the adult organism (Karson et al, 1992). These results, while preliminary, are important because they suggest alternative strategies in the treatment of human disease (Hall and Watt, 1989; Corn et al, 1991; Hollands, 1991; Diukman and Golbus, 1992).

Within the developing mammalian embryo are the totipotent cells of the late blastocyst which, after implantation, undergo commitment to specific developmental pathways and lineages (i.e., fates). While these cells are in many ways similar to the totipotent cells of the earlier embryo (e.g, cleavage-stage), they are irreversibly committed to developing into the tissue of lineage commitment. However, while these cells are "stem" cells, they may differ substantially from the stem cells found within the fully developed organism. Most importantly, embryonic stem cells must be highly proliferative while the stem cells of the adult are almost totally quiescent, and may be difficult or impossible to maintain and expand in culture. The results described in the citations listed above show clearly that at the least, some early embryonic stem cells may be expanded dramatically in culture and maintained for long periods of time. These results may have a fundamental impact on the treatment of a wide range of important human diseases. For example, it may be possible to establish cell lines from early embryos to serve as stem cells for bone marrow transplantation, as hepatic stem cells for the treatment of liver dysfunction, or neuronal stem cells that can be used in the treatment of nerve and spinal cord injuries. Indeed, some have suggested that organ transplantation may be replaced as the appropriate therapy in cases where the tissue could be reestablished by stem cell therapy. Current findings suggest that the early embryo-derived stem cells lack major histocompatibility antigens and therefore, it may be possible to circumvent cell transplant rejection. Because of the potential of such future therapy, it is important to begin to address the use of human embryos and early fetal tissues as a source stem cells, keeping in mind that cell lines would be established where a few embryos or tissue samples could yield sufficient proliferating cells to treat of many patients.

In order to derive such stem cells, early aborted tissue between 3 to 6 weeks of pregnancy may be a necessary source. In addition, such cell lines may be derived from prolongation of culture of preimplantation stage embryos. Indeed, it may be possible to direct embryonic differentiation to promote the proliferation of a specific stem cell type by molecular manipulations of the preimplantation stage embryo. Such manipulations may involve the introduction of genetic regulatory elements by recombinant and transgenic methodologies, and culture of early embryos in the presence of specific combinations of growth factors, such as nerve growth factor, or factors involved in hematopoiesis. In such cases, the duration of embryo culture should not include the proliferation of cells which no longer have totipotent ability. Although much of this research can be undertaken in model systems such as the mouse, at some time in the near future the possibility of clinical applications will be evident from methodologies and findings derived from animal research, and human embryo and fetal tissue will be required for experimentation. Consequently, very serious consideration needs to be given to the use of human material for stem cell research as this approach has the potential to offer a new strategy for the treatment of a wide range of human diseases.

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# Ethical Issues in Human Embryo Research

by

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## Introduction

Embryo and fetal research has not been federally funded since before the Reagan and Bush administrations, although research has continued, supported by private funds. Outside the United States, embryo research is funded and regulated. For example, Britain has set up procedures for reviewing embryo research through its Human Fertilisation and Embryology Act (HFEA), passed in 1990 (Morgan & Lee, 1991).

## Scientific Background

Research using human embryos falls roughly into three areas: (1) clinical research relating to *in vitro* fertilization, (2) basic or laboratory research, and (3) gene therapy.

*In vitro* fertilization and embryo transfer (IVF/ET) is now an accepted method of treating infertility. There are IVF clinics all over the world; thousands of babies have been born as the result of IVF/ET and its variations (Coutts, 1988). However, present success rates—measured in terms of creating live “take-home-from-the-hospital” babies—remain depressingly low. Even the most successful clinics treating the least-impaired couples with the most promising procedure, gamete intrafallopian transfer (GIFT), report rates only in the mid-30 percent range. The average success rate is between 12 and 20 percent (Robin, 1993). More clinical IVF research into improving existing techniques must be done if the rate of success is to improve.

Sperm microinjection is an example of a recently developed technique for treating male infertility. Immature sperm incapable of fertilizing an egg can be removed directly from a man's testicles, and inserted into the egg through an opening that has been drilled in the egg's outer coating (the zona pellucida). In the latest technique, a single sperm can be injected into the egg (Vines, 1993, p. 13). Techniques such as these cannot be developed without basic embryo research. Research on the embryo may also help improve understanding of the causes of infertility. Beyond the treatment of infertility, embryo research can play an important role in understanding cancer, developing better contraceptives, evaluating the effects of teratogens on the early embryo, and understanding normal and abnormal cell growth and differentiation (*EAB Report*, 1979).

Another area of research is on the embryo as “patient.” “This field results from the confluence of rapidly developing specialties in IVF, cytogenetics, embryo micromanipulation, and molecular biology” (Bonnicksen, 1991, p. 146). The discovery by researchers at Hammersmith Hospital in London and the University of York that removing one or two cells from an embryo at the

eight-cell stage does not harm the embryo or have any impact on its subsequent development (Vines, 1990, p. 30) has made feasible "pre-implantation diagnosis." A pre-implantation diagnosis would enable couples known to be at risk of having an affected child to avoid later tests during pregnancy, with the possibility of abortion. Instead, such couples could opt to have *in vitro* fertilization, and embryo biopsy. If the biopsied portion is normal, the embryo can be transferred to the uterus of the woman undergoing IVF. If abnormal, the embryo can be used in research or discarded. "Pre-implantation diagnosis is now feasible for a whole range of severe genetic diseases in which the genetic defect is well known, such as cystic fibrosis, Duchenne muscular dystrophy and thalassemia" (Vines, 1990, p. 30).<sup>1</sup>

Pre-implantation diagnosis does not attempt to treat the embryo, but rather to determine the existence of genetic defect or disease in order to avoid implanting a defective embryo. By contrast, embryo microsurgery manipulates an embryo to correct an abnormal condition. This requires new skills, procedures, and equipment. Clinical applications are likely by the end of the decade (Bonnicksen, 1991, p. 150). Another potential method of treating embryos is gene therapy. Gene therapy falls into two main categories: somatic cell gene therapy and germ-line gene modifications. Somatic cell therapy involves the correction of genetic defects in any of the cells of the body, with the exception of the germ or reproductive cells. One example of somatic cell therapy is the insertion of cytokine genes into a cancer patient's malignant cells to produce an immune response, the production of cytotoxic T cells that are specifically targeted to the tumor (Wivel and Walters, 1993, p. 533). Such therapy affects the patient only; the genetic modification is not passed on to offspring. It does not raise serious ethical questions beyond the need for rigorous safety testing and fully informed consent. Somatic cell therapy on human embryos is still a distant possibility. If a late stage embryo has a genetic defect that prevents cells from producing a certain hormone, for example, the abnormal cells could be removed and replaced with corrected stem cells (Bonnicksen, 1991, p. 151).

Germ-line gene therapy introduces changes in the genetic makeup of an individual that are passed on to at least one generation. At present, NIH guidelines forbid human germ-line research. A strong argument against germ-line research is the risk of unpredictable genetic side effects and irreversible mistakes. For example, such therapy might have subtle adverse effects on the brain that could appear many years after genetic intervention, in generations to come. Such effects might not be detected in animal models (Wivel and Walters, 1993, p. 537). Germ-line gene therapy has not yet been attempted in human embryos, but is used for commercial purposes in animals, for example, to yield larger than normal mice, or pigs that produce large litters, or pigs with a lower fat content. A research animal, Oncomouse, has been genetically engineered to produce offspring that rapidly develop tumors (Bonnicksen, 1991, pp. 151-152).

Before turning to the various specific arguments for and against different kinds of embryo research, we need to examine the most central and basic question, that is, whether it is morally permissible to experiment on human embryos at all.

## **Why the Moral Status of the Human Embryo Matters**

If the human embryo is a human subject, then it is entitled to the same protection as any other human subject. That does not mean that embryos could not be used in research. Human subjects are appropriately used in many different kinds of medical and scientific research. However, research on human subjects is strictly regulated. In particular, it is contrary to both law and ethics to experiment

on human subjects without their informed consent, or the informed consent of an appropriate surrogate (Appelbaum, Lidz, & Meisel, 1987, Chapter 11).

Since embryos cannot give consent to anything, the question is whether others (for example, its progenitors) can give consent on its behalf. This question is not unique to embryo research. It arises also in the case of minor children. It is well established that parents can consent to “therapeutic” research, or experimental therapies, on behalf of their sick children. Presumably, parents could also give consent for experimental treatments aimed at curing their diseased embryos. Somatic cell therapy might be a way of treating diseased or defective embryos at some point in the future.

It is more controversial whether nontherapeutic research (that is, research not intended to benefit the subject) on minor children is ever justified. Some ethicists, for example, Paul Ramsey, oppose all nontherapeutic research on children, because they are incapable of giving consent (Ramsey, 1976). By contrast, Richard McCormick thinks that parents may give proxy consent for a child to participate in nontherapeutic experimentation where there is no discernible risk or undue discomfort (McCormick, 1974). Both Ramsey and McCormick agree that fetuses have the same moral status as born children. But whereas Ramsey regards fetuses as vulnerable, helpless, and nonconsenting human subjects, precisely those whom regulations on experimentation are intended to protect, McCormick thinks that research on the living fetus is justified, so long as it poses no discernible risk or discomfort, appropriate consent from the parents is obtained, and the experiments are genuinely necessary for medical knowledge calculated to be of notable benefit to fetuses or children in general (McCormick, 1975, p. 5-4-5). Presumably, McCormick would have no objection to experimenting on, as opposed to discarding, embryos which could not be implanted.

If human embryos are not human subjects, then research on them for valid medical and scientific purposes (treating infertility, curing disease, etc.) is morally permissible. Indeed, banning or failing to fund such research might be immoral because there are millions of people who might have benefitted from the results of the research, had it been done (Harris, 1990).

## **The Moral Status of the Human Embryo**

The debate over the moral status of the embryo derives from the abortion debate. Those who are “pro-life” maintain that the embryo is a human being, or has human moral status. The pro-life position breaks down further into two camps: those who regard the embryo as a human being because it is genetically human, a member of the species *homo sapiens*, and those who ascribe its human moral status to its potential to develop into a human person, like you or me.

## **The Argument From Genetic Humanity**

Conservatives base their opposition to abortion on an argument that human embryos are human beings. The conservative’s argument has two parts. First, the conservative points to the fact that the embryo is indisputably genetically human. Moreover, it is not merely a human cell, like any cell in a human body. At fertilization, the egg and sperm combine to form a new genotype. From this single cell develop all the different types of tissue and organs that make up the human body. Fertilization thus marks the spatiotemporal beginning of a new human being.

Second, the conservative maintains that nothing that happens after fertilization has moral significance such that it would enable us to say, “Now we have a human being, but before this event it was not human.” Birth, viability, quickening, acquisition of human form, the appearance of brain waves—none of these milestones in pregnancy determine humanity. All of these events are just developmental stages in the life of the human being before birth. The conservative concludes that abortion, from fertilization onward, is the killing of an innocent human being and, as such, is seriously morally wrong.

## The Person View

Liberals on abortion typically deny that a human fetus, much less an embryo, has the same moral status as a born human being. Some liberals believe that the conservative position is based on a conceptual error, a confusion between two senses of the word “human.” That is, liberals acknowledge that human embryos are indisputably genetically human. However, this sense of “human” lacks moral relevance. According to person-view proponents, such as Mary Anne Warren, it is not genetic human beings who have a special moral status and a right to life, but *persons* (Warren, 1973). The fact that all the persons we know are also genetic human beings leads us to confuse the genetic and moral senses of the word “human.” However, on reflection, we realize that there could be persons who are not human (intelligent aliens, possibly chimpanzees), and humans who are not persons (anencephalics, patients in a persistent vegetative state). Therefore, to base moral status on the species to which one happens to belong is arbitrary and unjustified. Instead, we should recognize that moral persons are those beings who have certain capacities, including at least some of the following: sentience, consciousness, self-consciousness, reasoning, and language. Anyone who has all of these is a person, and anyone lacking in all these capacities isn’t a person, no matter to what species he or she belongs. Embryos have no person-making characteristics. Therefore, they do not have a right to life, and abortion is morally legitimate. Equally, embryos are not human subjects and may be used in research.

## The Argument From Potential

One response to Warren’s critique of the conservative position is the argument from potential, or the potentiality principle. The potentiality theorist is willing to acknowledge that a fertilized egg is not a person, like you or me, since it lacks any of the characteristics that makes us people. However, the fertilized egg has the potential to develop into an embryo, a fetus, and then a born human being. It is potentially just like us, and therefore entitled to the same protections we are. Potentiality theorists thus have the same objections to abortion and embryo research as conservatives.

The strongest objection to the argument from potential is that it leads to a *reductio ad absurdum*. If the objection to abortion is that it deprives the zygote of “a future like ours,” then contraception, which deprives gametes of “a future like ours,” is equally wrong. Few potentiality theorists are happy with this conclusion, and usually respond by arguing that gametes are not potential human beings in the way that embryos are. An embryo has a fairly good chance of developing into a person, if nothing external intervenes; the chances of a gamete becoming a person are much lower. Moreover, zygotes are naturally growing and developing into embryos and then fetuses. A gamete is not becoming anything. It is also argued that the born child is identified with the fetus and embryo in a way that it is not identified with the individual gametes prior to fertilization. Neither the sperm nor the egg has the same genetic code as the being who develops from their union, so neither is the same

being as the fertilized egg. Each of these arguments supporting the potentiality principle can be countered (see, for example, Steinbock, 1992, pp. 64-66). The literature on this point is extensive (see, for example, Buckle, 1988; Hursthouse, 1987; Marquis, 1989; Noonan, 1989; Warner, 1979), and the moral significance of potentiality is far from settled.

It is especially unclear what the implications of the potentiality principle are in the context of IVF. According to most potentiality theorists, embryos and fetuses are potential persons because they are developing into persons all by themselves. So long as nothing intervenes to stop the gestational process, the implanted embryo or fetus will become a person. By contrast, gametes are not growing or developing into anything other than what they already are. However, an extracorporeal embryo cannot develop into a person all by itself. It must be implanted in a uterus, with considerable outside intervention. In this respect, then, extracorporeal embryos resemble gametes, and are permissible subjects of research, if gametes are.

### **The Interest View**

A variation on the person view is the interest view (Steinbock, 1992). According to the interest view, beings have moral status if and only if they have interests. If a being has no interests, then its interests cannot be considered in moral deliberation. Without interests, a being cannot care what is done to it, nor can anything be done for its sake. The interest view differs from the person view in that neither self-consciousness, nor the ability to reason or use language, are essential for the possession of interests, and hence moral status. Thus, the interest view is less restrictive than the person view: for example, it considers both babies and animals to have moral status, although it does not insist that animals have equal moral status with human persons.

### **A Third Position: Embryos Have Symbolic Value**

A compromise between the conservative and liberal views of the embryo is to maintain that although embryos are not persons, they have moral value as a form of human life. On this view, abortion is both morally permissible and morally serious.<sup>2</sup> Applied to research on embryos, the third position holds that such research should be done for valid scientific and medical purposes, but embryos should not be frivolously or unnecessarily used in research.

This third position has been the view of several important official bodies. The Ethics Advisory Board in the United States (1979) found that "the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons" (*EAB Report*, 1979, pp. 35-36). The Warnock Committee in Great Britain (1984) maintained that "the embryo of the human species ought to have a special status" and "should be afforded some protection in law" (Warnock, 1985, p. 63-64).

Proponents of the third position also support restrictions on embryo research such as time limits. The Warnock Committee recommended limiting research on human embryos until the appearance of the primitive streak, at about 14 days. The appearance of the primitive streak, which coincides with implantation during gestation, has moral significance for many people. They argue that even if the implanted embryo is granted moral status and rights, the same moral status should not be extended to pre-implantation embryos. This argument is based on identity. Pre-implantation embryos are undifferentiated aggregates of about eight cells. Most of the cells of the pre-embryo

develop into a trophoblastic or feeding layer that becomes the placenta; only a small minority become the embryo proper which develops into the fetus. Thus, the pre-embryo is not identical with the embryo that develops into the fetus, and later the child. Moreover, prior to the development of the primitive streak, twinning may still occur. Since it is possible that the pre-implantation embryo will become two individuals, it is argued that it cannot be identical with the fetus or the person who later is born. Identity is established only after implantation, when twinning is no longer possible. Pre-implantation embryos are held not to be potential persons, and therefore they may properly be used in scientific and medical research. The other reason for thinking that implantation has moral significance has to do with the capacity for sentience. The pre-implantation embryo has not yet developed the embryonic disc, axis, or primitive streak, which are the rudimentary structures of a nervous system. The capacity to experience pain is not only extremely unlikely at this stage, as it is with an early-gestation fetus; it is physically impossible. Therefore, there is no reason to be concerned that research on the pre-embryo can cause it to suffer.

## **Ethical Issues in IVF Research and Practice**

### **The Risk of Abnormality**

When IVF was in its infancy, a number of critics objected to the procedure on the grounds that it was immoral to run the risk of producing a congenitally abnormal baby, a risk that was at that time unknown. Defenders of IVF rejoined that animal studies indicated that the risk of abnormality was no greater with IVF than with normal conception. Moreover, they argued that abnormal embryos would be unlikely to implant.

Although most of the debate centered on whether IVF was likely to result in deformed offspring, John Robertson took the position that it is no objection to IVF that it might have these results. For if IVF were not done, the child would not get born at all, and nonexistence is almost always worse for the child than existence.

From the child's perspective, the only alternative to the action that allegedly violates his right not to be harmed is even less desirable, for it means no existence at all. One does not respect a person's rights by refraining from an activity that prevents his existence altogether (Robertson, 1978, p. 14).

According to Robertson, the resulting offspring is harmed and wronged only if the damage caused by IVF is so severe, and the child's life so fraught with pain and suffering, that the child might find death preferable.

Others disagree with Robertson. They maintain that no one is harmed by not being brought into existence. By contrast, bringing children into existence who suffer from crippling or painful diseases does harm them, even if they prefer to go on living to being killed. Therefore, the risk of serious defect or disability is a *prima facie*, if not a conclusory reason, against bringing such a child into existence (Steinbock and McClamrock, forthcoming). It matters very much whether IVF poses a significant risk of causing children to be born with serious defects.

In the first decade since the birth of Louise Brown, the first IVF baby, the fears of deformed offspring appear not to have proved well-founded. IVF so far has shown no higher rate of congenital deformity than coital reproduction (Robertson, 1986a, p. 991). A study published in August 1989 in

*The Journal of Pediatrics* revealed that babies conceived in a laboratory were as healthy as those conceived normally (Morin et al, 1989).

However, data from the National Perinatal Statistics Unit in Sydney, Australia suggest that IVF children are two or three times more likely to suffer from certain birth defects, notably spina bifida and heart abnormalities. This unit has collected comprehensive statistics on IVF children since the late 1970s. The number of births recorded in Australia is still too small to know whether the differences are statistically significant. The problem is getting adequate numbers in a country with a relatively small population, according to Paul Lancaster, director of the unit. He has long campaigned for international collaboration as the only way to collect sizable numbers reasonably quickly (Vines, 1993, p. 14).

Although Britain has had regulations governing IVF and embryo research since the mid-1980s, Britain has no system of following up children who have been born as a result of these techniques. Without long term studies of the children, it will be impossible to tell when the techniques are safe. For example, sperm microinjection looks safe, but the only way to be sure is to look at the outcome—the babies. It is of the utmost importance that bodies debating regulations for embryo research also recommend **follow-up studies** on the subjects of embryo research, as well as **international collaboration** on IVF data.

## **Spare Embryos**

A major ethical problem concerns the disposition of surplus or spare embryos. There are sound medical reasons for creating more pre-embryos than can be implanted, but this means discarding or using in research the spare embryos. This is considered morally intolerable by those who regard pre-embryos as human persons.

Researchers have found that the ideal number of pre-embryos to insert in the uterus at one time is three or four. Fewer than that reduces the chances of achieving a pregnancy. More than that increases the risk of multiple births. This is not only undesirable from the perspective of many prospective parents, but involves health risks for the mother and babies. Multiple births are associated with low birthweight. Low-birthweight babies have a significantly higher mortality rate than full-birthweight babies; for example, they are ten times more likely to die from intrapartum asphyxia (Weir, 1984, p. 40). A recent study published in *Pediatrics* found that twins are almost 12 times as likely as single-birth babies to develop cerebral palsy ("Risk of Cerebral Palsy Found Higher for Twins," 1993).

For health reasons, then, fertility doctors are unwilling to implant more than three or four pre-embryos. However, there is no guarantee that the three or four pre-embryos will implant. If the doctors have retrieved and fertilized only the number of eggs they are willing to implant, and a pregnancy is not achieved, the patient will have to undergo another treatment cycle—perhaps several—in order to achieve a pregnancy. This means repeated exposure to drugs to stimulate her ovaries, and invasive procedures to retrieve the eggs and insert the pre-embryos. This is both expensive (a single attempt at IVF costs between \$5,000 to \$12,000, depending on location) and risky for the woman. The common side effects from drugs such as Pergonal include bloating, weight gain, fatigue, hot flashes, depression, and mood swings. Ovarian overstimulation, in which the ovaries become enlarged and produce too many follicles, is a severe side effect which happens to about one in five women being treated with Pergonal. Even more dangerous is ovarian hyperstimulation, which

happens in 1 to 2 percent of women, in which the ovaries become enlarged, blood hormone levels skyrocket, and excess fluid may collect in the abdominal cavity or in the lungs. Cysts that have formed within the ovaries may rupture, causing internal bleeding. Rarely, blood clots will develop, which can be fatal (Robin, 1993). Repeated treatment cycles also increase the risk of complications from the invasive procedures used in egg retrieval or insertion of a pre-embryo, including bleeding, adverse reaction to anesthesia, and infection. In addition, there is some evidence from Australia that some drugs used to stimulate a woman's ovaries may enhance her risk of ovarian cancer (Vines, 1993, p. 14).

Medically, the obvious thing to do is to extract more eggs—perhaps as many as twenty or thirty—during a single treatment cycle, and to fertilize all of them. The doctors could then select the healthiest pre-embryos, those that appear to have the best chance of implanting. Any other healthy embryos could be frozen for future use by the couple, in case none of the first batch implanted. Any embryos that appeared not to be developing normally could be discarded or used in research. If the couple did not need the surplus frozen embryos because pregnancy was achieved the first time, or because they decided not to pursue having a child via IVF, the extra embryos could be donated, discarded, or used in research. The only reason for not doing this is to avoid discarding surplus embryos. Most American IVF programs do not fertilize more eggs than they plan to place in the uterus to avoid adverse publicity and controversy with right-to-life groups.

## Cloning

Researchers from the George Washington University Medical Center, led by Jerry Hall and Robert Stillman, sparked a firestorm of controversy, when they reported at the joint annual meeting of the American Fertility Society and the Canadian Fertility and Andrology Society in October 1993 that they had produced the first reported test-tube-generated twin of a fertilized human egg. The headline in *The New York Times* read “Scientist Clones Human Embryos, and Creates an Ethical Challenge” (Kolata, 1993, p. A1). What precisely was the ethical challenge?

To answer this question, we must first understand what was done. There are two ways to clone embryos. The first is to divide the early embryo into two and possibly four separate viable embryos. It is not possible to get more than four embryos because the mass would then develop into a non-viable trophoblast lacking any inner cell mass and hence any embryo (Ferguson, 1990, p. 22). The other approach to cloning involves fusing individual embryonic cells with unfertilized eggs from which the nuclei has been removed. This process, called nuclear transplantation, imbues the second egg with the genetic characteristics of the first (Kolata, 1993a, p. 22). It ensures that each new embryo has an intact zona pellucida, which is necessary for implantation and development. But that procedure is not practical for human embryo cloning because there isn't a ready supply of human eggs from which the nuclei can be removed. Then, in 1991, Hall and his colleague Sandra Yee showed that it was possible to coat separated embryonic cells with a synthetic zona pellucida, opening the way to human embryo cloning (*Science*, 1993).

The George Washington researchers took 17 embryos, at the two-to-eight cell stage, obtained from women undergoing IVF treatment. After separating the individual embryonic cells, called blastomeres, and coating them with the artificial zona pellucida, Hall and his colleagues placed the blastomeres in nutrient solutions where they could begin dividing again. The result was 48 new embryos, an average of three for each original embryo.



Many ethicists were appalled. Cynthia Cohen, Executive Director of the National Advisory Board on Ethics in Reproduction, was reported in *The Wall Street Journal* as saying that creating a human double of an existing embryo was "contrary to human values" (Waldholz, 1993, p. B7). But why is this? What precisely is wrong with cloning?

On the most extreme conservative position, the embryo is a human person, and must not be used in any nontherapeutic experimentation. However, few opponents of cloning espouse the conservative conception of the moral status of the embryo. They are not opposed to embryo research in itself, but rather specifically to cloning embryos. It may be that the term, "cloning," is itself partly responsible for the opposition. The idea of cloning in the popular mind is of an evil dictator attempting to populate the world with his replicas, or hundreds of thousands of mindless individuals created by mad scientists to perform various tasks. However, as Singer and Wells point out, "If some mad dictator wished to program groups of people, it would be a pointless and expensive exercise to have them cloned first. Identical twins are not more susceptible to brainwashing techniques than single births, and no more would cloned individuals be" (Singer and Wells, 1985, pp. 141-142).

Singer and Wells maintain that it is important to distinguish between cloning done for the purpose of producing living human beings and work that has no such intention.

The most powerful reasons for cloning are to enable embryos to be genetically typed and to provide compatible tissues and organs for medical purposes. Moreover, the objections to cloning are weakest when directed against these forms of cloning. Since neither leads to a living human being, we can disregard objections based on the risk of an abnormal child or on the psychological problems that might face a cloned person (Singer and Wells, 1985, p. 147).

The cloning done by Hall and Stillman could not have led to the birth of a child, and hence any objections about the risk of physical or emotional problems of such a child do not apply. The researchers chose for their experiment embryos with a fatal defect: they were formed from eggs fertilized by more than one sperm, giving them three or more set of chromosomes instead of two. Such embryos cannot be implanted and are certain to die. The longest-lasting embryos in the Hall-Stillman experiment survived only a few days to the 32-cell stage. "We used these triploid embryos so as not to get into an ethical debate," Hall said (Miller and Vines, 1993). The inability of the embryos to survive more than a few days was important in getting the approval of the hospital's ethics committee. According to the head of the committee, Gail Povar, "What we're talking about here is nonviable human chromosomal tissue. I don't consider this to be human cloning. I consider it the manipulation of pathological specimens" (Miller and Vines, 1993).

Still, some are afraid that cloning triploid embryos is only the first step. They oppose this sort of experimentation because they fear the logical next step: cloning an embryo for implantation. In July, 1993, the British Human Fertilisation and Embryology Authority, which has the power to grant licenses for procedures using embryos, decided that splitting human embryos is "ethically unacceptable" and should not be allowed. Nor was this a new position. The British Medical Association's statement of May 1983 says that cloning is "ethically unacceptable" if there is any intent to transfer multiple progeny to a uterus. This echoes the view of the Australian National Health and Medical Research Council which said, "Cloning experiments designed to produce from human tissues viable or potentially viable offspring that are multiple and genetically identical are ethically unacceptable" (cited in Singer and Wells, 1985, p. 146).

Not everyone opposes cloning human embryos for transplantation. Andrea Bonnicksen writes, "If [embryo] biopsy is shown to be safe, a logical extension of the technique will be to "twin" an embryo, as is already done in animal husbandry, and create a "duplicate" embryo to be preserved and transferred to the woman in the event the first embryo fails to implant" (Bonnicksen, 1991, p. 149). From this perspective, cloning is simply another method for obtaining more embryos for implantation in IVF/ET, no different from extracting and fertilizing eggs. Moreover, it has the advantage of not inducing superovulation in women, with all of its attendant risks, in order to extract a sufficient number of eggs. Embryo cloning is a way to produce multiple embryos without the cost, side effects, or possible risks associated with hormone treatment.

Given these advantages, why the opposition to cloning? The objection seems to be that it could lead to "Brave New World" scenarios. For example, parents might be able to save identical copies of embryos so that, if their child ever needed an organ transplant, the mother could give birth to the child's identical twin, a perfect match for organ donation.

Would this be morally wrong? Something analogous was done a few years ago by the Ayala family, when Mary Ayala conceived a child specifically to be a bone marrow donor to her older sister, Anissa, who was dying of leukemia. The reaction from medical ethicists was generally negative; the Ayalas were seen as treating the new baby as a "mere means," contrary to Kantian ethics. However, it can be argued that conceiving a baby to serve as a donor is not necessarily treating her as a mere means, so long as her family will love her as a person in her own right once she is born, and the donation does not impose unacceptable risks on her (Steinbock, 1990). If Anissa already had a baby sister with compatible bone marrow, her parents could undoubtedly ask the doctors to do the transplant to save Anissa's life. Why should the moral situation be different if their choice is to try and conceive a sibling with compatible marrow?

One important difference between the Ayala case and cloning a twin as a source of a replacement organ, such as a kidney, is that, unlike bone marrow, kidneys are not replenishable. There is far more risk to the donor in going through life with only one kidney than there is from donating bone marrow. In general, a marrow transplant represents little risk to the donor. Baby Marissa came out of the procedure with only an ache in the hip. By contrast, donating a kidney requires major surgery and imposes significant risks. Courts have generally been reluctant to allow minors incapable of giving consent to serve as organ donors for siblings. These considerations militate against creating a twin embryo to be saved for future gestation as a potential source of spare parts. But what if no new person was created? Would it be morally permissible to clone an embryo as a source of cells or tissue to implant into the adult at some future time, to correct some failing system? This might be done at some time in the future to treat diabetes or Parkinson's disease. Since it would not involve making a new person as a source of spare parts, this scenario should not disturb those who do not consider embryos to be people. However, it is not clear what the scientific rationale for doing so would be. One of the advantages of embryonic (and fetal) tissue is its immunological compatibility. The lack of antigens and passenger leukocytes means that embryonic and fetal tissue are less likely to evoke an immune reaction leading to rejection than are adult tissues. Therefore, there is no need to clone a genetically identical embryo as a cell or tissue source. Indeed, in autoimmune diseases, such as diabetes, a family member's cells are uniquely *unsuited* for transplant (Fine, 1988, p. 6), so presumably the cells from one's clone also would be.

Another worry is that parents might store cloned embryos as replacement children. For example, they could keep a frozen embryo as a backup in case their child died, so they could create the perfect replacement. However, parents who store an extra embryo for this purpose are likely to

be sorely disappointed. Even though the two embryos would be genetically identical, the resulting children would not be. The reason is that cytoplasm plays a role in directing gene expression, and so cells created by nuclear transplantation are never identical to the donor because of this cytoplasmic difference (Ferguson, 1990, p. 23). Moreover, the embryonic environment has large influences on the development of the embryo. Consequently, genetically identical embryos allowed to develop in the same mother at different times would not turn out to be identical. Environmental differences also come into play. That is why identical twins, gestated at the same time, never have identical personalities (Singer and Wells, 1985, p. 141), and often do not look exactly alike either.

The same response can be given to the objection raised by Dr. Arthur Caplan, director of the Center for Bioethics at the University of Minnesota, that cloning is "morally suspect" because it allows us to know what someone will be like in the future.

Twins that become twins separated by years or decades let us see things about our future that we don't want to. You may not want to know, at 40, what you will look like at 60. And parents should not be looking at a baby and seeing the infant 20 years later in an older sibling.... Is that fair to the child? What expectations will you put on them? (Kolata, 1993b, p. C3).

Relatives often do resemble each other (which is why it used to be said, in a more sexist age, that before marrying a woman, a man should take a good look at her mother). The fact that cloned individuals are likely closely to resemble each other, as twins do, does not seem to raise unique or especially troubling ethical problems. Twins are not exact replicas of each other, and so cloning does not let us see our futures, even if that were thought to be a very bad thing.

A related objection was raised by Dr. Edward L. Marut, the medical director of the *in vitro* fertilization center at Michael Reese Hospital in Chicago, who said he could not imagine offering cloning. "You have to draw a line at some point. It's a dangerous turn, trying to create a perfect child and then duplicating it. What do you do if you don't like the first child? Throw the cloned embryo away?" (Kolata, 1993b, p. C3). It is not clear why parents who have conceived using IVF/ET should expect that they have created a perfect child, any more than parents who conceive in the ordinary way. In any event, as already noted, they should not expect the cloned embryo to be a replica of the first child. It is not possible to duplicate a child.

Identical twins who are born years apart are indeed novel, but it is not clear that the procedure raises any special ethical questions. At the same time, cloning may not make sense from a scientific standpoint. According to Alan Handyside, a senior embryologist at the Hammersmith Hospital in London, cloning does not increase the chances of an embryo implanting, but probably reduces them. He says that implantation rates decline rapidly in mouse embryos that have been experimentally divided. According to Handyside, splitting human embryos might also increase the risk of multiple births (Miller and Vines, 1993). These scientific questions need to be settled before deciding whether cloning is a good technique for producing embryos for IVF/ET. At the same time, it should not be assumed that there is no scientific value in cloning embryos because the idea makes some people uncomfortable.

## **The Social Utility of Fertility Treatments**

A very different sort of objection to IVF and related procedures comes from some feminists. They argue that treating infertility as a serious disorder meriting expensive, invasive treatment stems from and fosters a pronatalist ideology (Corea, 1985). They also object to the “technologizing” of conception and childbirth, and taking these out of the hands of women (for a discussion of this objection, see Robertson, 1986a and Warren, 1988). In addition, they point to the relatively low success rate of IVF (U.S. Congress, OTA, 1988, p. 10), and maintain that the presentation of IVF as a acceptable treatment for infertility lies to and exploits women. Many commentators are concerned about the health risks for women (Rothman, 1992). Finally, some commentators, while not objecting to IVF intrinsically, regard funding IVF research as a low priority in a society where basic health needs of existing people are not being met. They also point out that attempts to reduce some of the causes of infertility, including sexually transmitted diseases, such as chlamydia, would be cheaper and affect greater numbers of women, than IVF.

## **Detecting Genetic Disease in Embryos**

### **Dilemmas of Prenatal Testing**

Some day, it may be possible to correct disorders detected by screening embryos. For now, the usual course is for parents to opt for termination of the pregnancy. This is obviously unacceptable to pro-lifers, who oppose abortion generally. They would no more condone abortion for genetic indications than they would support killing children with genetic diseases.

Some people who are generally pro-choice are opposed to the idea of prenatal testing and abortion for genetic indications (Rothman, 1986). Rothman is particularly opposed to amniocentesis, since it cannot take place until about 16 weeks gestation, after the pregnancy is well established. This places the pregnant woman in a peculiar and stressful psychological situation, where she is both committed to the pregnancy and prepared to abort if the fetus is affected.

Embryo replacement would not raise any concern about “tentative pregnancies,” since the embryos are created *in vitro* and the defective ones are discarded before being implanted in the woman’s uterus. Indeed, an important advantage of IVF/ET is that it spares at-risk couples the emotional trauma of an abortion in the fifth month of pregnancy. However, Rothman has another objection to “eugenic” abortion, one that is not alleviated by very early prenatal testing or embryo replacement following IVF. She worries that genetic testing will become so accepted as no longer to be a choice for the pregnant woman. She is concerned that there will be increasing social pressure not to bring a handicapped child into the world.

A similar position is taken by Adrienne Asch, who supports services for the disabled, rather than termination of pregnancy. Asch views the acceptance of abortion to prevent disability as evidence and reinforcement of the attitude that disabled people are not full-fledged members of society. Other commentators disagree, arguing that prospective parents do not have the same obligations to fetuses that they have to actual children. If it is morally permissible for women to abort to avoid interrupting a career or financial hardship, they are equally entitled to abort to avoid the arguably greater burdens of caring for a disabled child (Steinbock, 1992, pp. 206-208).

This raises the question of whether genetic screening should be used only for serious disorders and diseases, or whether parents should be able to screen and replace for less serious conditions, such as a cleft palate. John Robertson argues that restrictions on embryo biopsy would be invalid under *Roe v. Wade*:

... because embryo screening provides information that will determine whether a woman will have embryos placed in her body. If she has a right to refuse placement or to terminate pregnancy, and the right to prenatal diagnosis after pregnancy has begun, then she should have a right to receive information that is material to a decision to have embryos placed in her body (Robertson, 1990, p. 508).

In a footnote, Robertson explicitly says that this includes a right to information about the gender of the embryo, “unless a compelling reason to withhold that information could be established.”

In other words, if procreative liberty gives women the right to abort through the first two trimesters for any reason whatsoever, it is hard to see what justification there could be for putting limits on genetic screening and nontransfer of embryos. Some may argue that it is morally wrong to reject an embryo because of a minor imperfection. An individual who would be unwilling to have a child with even a minor defect might be criticized as wanting a “perfect child.” Someone who does not want a child with even minor defects may not be capable of the sort of love parents are supposed to have for their children. However, we may wish to distinguish between abortion to avoid minor defects and embryo replacement. We have already noted the position that abortion is both permissible and morally serious. On that view of abortion, there seems something very callous about having an abortion to avoid having a child with a minor defect. It is less clear that it would be equally callous to discard an embryo for this reason. Since selection is part of the transfer process—i.e., not all the fertilized eggs can be transplanted—it is not unreasonable to choose the “best,” the “healthiest,” the “most perfect” of the lot.

Screening for sex selection is troubling to many people because it suggests that one sex is better than the other. Since the preferred sex is usually male, this is thought to reinforce sexist attitudes and the oppression of women. Others argue that there are real differences between boys and girls, so that it is not unreasonable to have a preference for one over the other. Another concern is that sex selection could lead to an imbalance between the sexes. Some worry about the problems this could cause, while others argue that any imbalance will naturally right itself (Singer and Wells, 1985, pp. 152–153).

## **Transgenic Babies**

Because the genes of all organisms are made of the same chemical—DNA—genes of different origins can be recombined and edited in the laboratory. Genes created in this way and insert into a new embryo are called transgenes. These genes will be present in every cell as the embryo grows, and they can exert their effects throughout an organism’s lifetime. Used to replace a defective gene in an animal embryo, transgenes can prevent the symptoms of an inherited disease (Pollack, 1993).

An animal that contains non-parental DNA is called a transgenic animal. The production of transgenic animals has opened new lines of experimental investigation. Transgenic organisms provide a powerful new tool for investigating basic scientific questions such as how oncogenes co-operate and complement each other; the tracing of embryonic cell lineages (i.e., what cells in the adult are derived

from what pieces of the embryo); the tissue specific expression of certain genes (i.e., why certain types of cells only develop in certain regions of the body); the development of the body pattern (i.e., how tissues such as the hand and foot, both of which are composed of identical tissues, come to have different patterns), and the coordination and regulation of growth (Ferguson, 1990, pp. 12-14).

In addition to basic research, the insertion of genes into animals or human beings can be used in gene therapy. Gene therapy is concerned with treating genetic disease by the replacement or correction of a defective mutant gene (Elias and Annas, 1987, p. 267). There are four potential levels of application of genetic engineering for the insertion of a gene into a human being: somatic gene therapy, germ-line gene therapy, enhancement genetics, and eugenic genetic engineering.

Somatic gene therapy is the least controversial. It involves replacing a non-functional gene with a functional gene for the treatment of diseases caused by single gene defects. The replacement gene is inserted into the somatic cells and it has no effect on the germ (reproductive) cells. Although it is still in the experimental stages, somatic gene therapy has already been successfully done on human beings. "On September 14, 1990 a four-year-old girl who lacked an enzyme required to keep immune cells alive and functioning became the first human to undergo gene therapy.... More than one year later she is alive and doing well" (Munson and Davis, 1992, p. 137). Both the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and the European Medical Research Councils concluded that somatic cell gene therapy is not fundamentally different from other therapeutic procedures. NIH committees overseeing the research now approve somatic cell therapy so long as safeguards needed in any experimental procedure are followed and protocols pass appropriate review.

Germ-line gene therapy is intended to alter the genetic constitution of specific individuals and their descendants. It has not yet been done, partly because it faces enormous technical difficulties, but also because it is ethically much more controversial. The effects of such therapy will affect not only the individuals treated, but their descendants, who cannot possibly give consent, informed or otherwise, to the therapy. Some regard this as an absolute barrier to the permissibility of germ-line gene therapy. Even if the therapy will be beneficial, they maintain, it is impermissible, because to change people's genetic structure without their consent violates their autonomy.

It has been responded that members of future generations do not yet have any autonomy that could be tampered with. "So there is nothing to protect by requiring their 'informed consent'" (Munson and Davis, 1992, p. 143). In addition, if we take the informed consent line of argument to its logical conclusion, it seems to require that individuals abstain from reproducing entirely, since we have not received the informed consent of future progeny that they wish to be born at all! The conclusion seems to be that it is not necessary to get the consent, informed or otherwise, of non-existent people in order to bring them into existence or to improve their lives once they arrive. Opposition to germ-line gene therapy based solely on the lack of informed consent from future generations is implausible. Instead, such opposition must be based on the risk of harm to future generations.

Does germ-line gene therapy pose a risk of harm? Certainly the intent is to make future people better off by preventing crippling, painful and fatal diseases:

If germ-line gene therapy were possible, practical, and widely employed, hundreds of genetic diseases might be eliminated from families. In each case, it would be possible for the disease to occur again through mutation, but the risk would be no

greater than in the population at large, and the total number of cases needing somatic cell or other therapy would be greatly reduced. Horrible diseases like Lesch-Nyhan, PKU, and Tay-Sachs would simply disappear as a nightmarish heritage in certain family lines (Munson and Davis, 1992, p. 139).

These benefits must be balanced against the risk of mistake. The possibility of unforeseen errors has led some commentators to suggest that unless there is overwhelming evidence that the procedure will be successful and not cause harm to the resulting child, or future children, there is no justification for doing genetic experiments on an early embryo and then implanting it. "The more reasonable position would be not to reimplant the genetically defective embryo in the first place" (Elias and Annas, 1992, p. 146).

Scientists have already found some unexpected errors in genetic experiments on animals:

Recently, for example, scientists interested in coloring the hair and eyes of an albino strain of mice injected the gene for a pigment; unexpectedly, they created a strain of mice whose viscera—heart, stomach, liver, and the like—were all turned around. These mice were unable to live long after birth; the added gene had inadvertently damaged a gene responsible for the usual positioning of the internal organs (Pollack, 1993).

Pollack goes on to warn of the accidental introduction of a more subtle mutation in a transgenic child might present us and our descendants with the task of dealing with a new inherited disease. He concludes, "Since responsible scientists cannot promise that all their first experiments will work, I do not see how transgenic medicine can ever be ethically launched" (Pollack, 1993).

Another objection to germ-line gene therapy is that what may be considered a harmful genetic trait could conceivably serve a beneficial function. The usually cited example is sickle cell trait which can cause a crippling and fatal disease in the offspring of two carriers, but also protects carriers against malaria. Munson and Davis argue that the benefits of eliminating sickle cell disease might outweigh the benefits of immunity to malaria, since we have treatments for malaria and none for sickle cell disease. But what about connections between diseases and important biological capacities of which we are unaware? Tampering with the germ-line may produce results whose full significance we cannot know in advance. To this, Munson and Davis respond:

No one can guarantee that an unexpected hazard might not result from germ-line gene therapy. However, we are not totally ignorant of the nature of genes and of the evolutionary process, and there is no reason to fear that germ-line therapy is more likely to produce an unanticipated disaster than is somatic cell therapy or any other use of recombinant DNA therapy. These matters must be assessed in individual cases on the basis of acquired knowledge and experience (Munson and Davis, 1992, p. 148).

## **From Therapy to Enhancement**

Some commentators think that gene therapy, whether somatic or germ line, is appropriate for the treatment of serious diseases, but draw the line at "enhancement genetic engineering." That is, we should not use gene therapy to make people taller or smarter or kinder. The argument is that the

risk of horrendous error is simply too great to permit tinkering with genes for enhancement purposes only. The trouble with insisting that gene therapy be restricted to the amelioration of disease, as opposed to the enhancement of traits, is that the line between the two is fuzzy. Sheldon Krimsky says, "Any trait that has a higher association with the onset of a disease may itself be typed as a proto-disease, such as fibrocystic breasts" (Krimsky, 1991). In any event, the use of gene therapy for enhancement may not be a practical possibility. The traits one might want to enhance, such as intelligence, are not only polygenic, but also partly determined by environment. It is far from clear that intellectual ability could be determined by genetic modification.

Germ-line gene therapy remains controversial. Some of the opposition is opposition to any manipulation of the human embryo, based on the assumption that the embryo is a human person. Others are afraid of a "slippery slope," that genetic tampering to eradicate disease will lead to positive eugenics. Positive eugenics is disturbing to many people because it is reminiscent of the Nazi racial theories, and their horrible acts to put them into practice. The idea of improving our species inevitably seems to be linked with ideas that some people are inferior and should not procreate. The dangers of discrimination seem great. Perhaps the greatest fear is the danger of creating a new defect or disease that will be passed on from generation to generation. In light of these worries, Sherman Elias and George Annas make the following recommendations prior to attempting any human germ-line gene therapy:

1. Germ line gene experimentation should be undertaken only to correct serious genetic disorders (such as Tay Sachs disease).
2. There should be considerable prior experience with human somatic cell gene therapy, which has clearly established its safety and efficacy.
3. There should be reasonable scientific evidence using appropriate animal models that germ-line gene therapy will cure or prevent the disease in question and not cause any harm.
4. Interventions should be undertaken only with the informed, voluntary, competent, and understanding consent of all individuals involved.
5. In addition to approval by expert panels such as the NIH's Working Group on Gene Therapy and local Institutional Review Boards, all proposals should have prior public discussion (Elias and Annas, 1992, pp. 151-152).

## **Creating Embryos for Research**

Most American fertility centers attempt to fertilize only as many eggs as can be implanted. However, sometimes more eggs are fertilized than expected, and so some embryos created during IVF cannot be transferred. Others cannot be implanted because they are defective. These "spare" embryos can be discarded or used in research. An issue that was discussed at great length by the Warnock Committee was whether it is permissible to go beyond using spare embryos, to create embryos specifically for research purposes. Some members of the Committee were opposed to any embryo research at all, based on the embryo's potential to become a person. This group was even more adamantly opposed to the creation of embryos for research. A second group did not distinguish between spare and research embryos. A third group saw a clear moral distinction between using



spare embryos and creating embryos for research. They argued that it is inconsistent with embryo's special status as a form of human life that it should be caused to exist, with no possibility of implantation (Warnock, 1985, p. 67).

This third group based their opposition to creating research embryos on two arguments, one based on appeal to a slippery slope, the other based on the doctrine of the double effect. The first argument begins by stating that frivolous and unnecessary research on embryos should be prohibited. However, if embryos can be created for the sole purpose of research, this opens the way to using human embryos for routine and less important research. "Once a foot is set on the 'slippery slope' of deliberate creation of embryos, no end can be set to the dangers" (Warnock, 1985, p. 67).

In response, it can be said that slippery-slope arguments are faulty because they assume, without justification, that it is impossible to set limits and create restrictions that will prevent the predicted dire consequences (Gorovitz, 1982, pp. 167-168). Moreover, even putting aside general problems with slippery-slope arguments, no reason is given why creating embryos for research should put us on the slippery slope toward unnecessary research.

The second argument appeals to the doctrine of the double effect, which says that an act that would be wrong if chosen for its own sake may be justified if it occurs as the by-product of some other, well-intentioned act. Research on spare embryos is permissible, since these embryos are created for a legitimate purpose, namely, establishing a pregnancy. Research on embryos created specifically for experimentation, however, is wrong.

The trouble with this argument is that it simply assumes that it is wrong to experiment on embryos, and to create them for that purpose. But why is it wrong? Perhaps the idea is that embryos, while not quite persons, are sufficiently like persons to make it wrong to experiment on them without their consent. But this argument would also rule out experimenting on spare embryos. Another argument is that it is repugnant to create human life solely for the purpose of destroying it in embryo experiments. However, research embryos are not created solely for the purpose of destroying them in experiments. The purpose of the experiments is to gain knowledge that will enable to save lives and prevent misery. It isn't clear why this purpose is not as legitimate as establishing a pregnancy.

Perhaps the idea is that creating an embryo to establish a pregnancy is to do something for its sake, whereas creating an embryo for research is to use the embryo to benefit others, and thus treat it merely as a means, which is inconsistent with according it the respect due to persons (and perhaps potential persons). On the interest view, however, embryos do not have interests of their own, and therefore cannot be harmed or benefitted, either by IVF or by research. Creating embryos for valuable scientific research is as permissible as creating them with the intention of establishing a pregnancy (Steinbock, 1992, pp. 210-211).

## **Dispositional Problems**

The ability to freeze surplus embryos for future use means that patients can have a second or third chance at pregnancy without having to undergo another laparoscopy for egg retrieval. It also creates the problem of what to do with unused frozen embryos. Should they be donated to women who cannot produce their own eggs?<sup>3</sup> Discarded? Or used in research?

Most jurisdictions have not faced this issue. Laboratories simply keep embryos frozen in liquid nitrogen; there are probably thousands of frozen embryos all over the world. Their disposition becomes an issue only when property rights or custody must be resolved. Advance agreements, such as those required in the 1990 British Human Fertilisation and Embryology Act (Morgan and Lee, 1991, p. 137) will go a long way to avoiding legal problems. However, like wills and prenuptial agreements, advance agreements on the disposition of frozen embryos can be challenged. When such cases come before the courts, judges will have to decide how to consider extracorporeal embryos: whether they are property, preborn children, or something else.

In the famous *Davis v. Davis* case, the trial court judge, W. Dale Young, maintained that the frozen embryos were people, and attempted to apply a "best-interest" analysis. He held that it was in the best interest of these "children" that they be available for implantation, and that their "mother" be permitted to bring them to term.

To see the implausibility of this approach, consider the following example from George Annas. If a fire broke out in a laboratory where the Davis's embryos were stored, and a two-month old child was also in the laboratory, and only the embryos or the child could be saved, would anyone hesitate before saving the child? Of course not. This shows that no one really does equate embryos and children, and the absurdity of a "best interests" analysis applied to blastocysts (Annas, 1989, p. 22).

Judge Young's decision was bad law and bad bioethics. This was recognized by the Tennessee Court of Appeals, an intermediate-level appeals court, which overturned Judge Young's decision awarding disposition of the embryos to Mrs. Davis. The appellate ruling was upheld in a unanimous decision by the Tennessee Supreme Court on June 1, 1992. A year later, on June 10, 1993, Junior Lewis Davis disposed of the embryos. In its decision, the Tennessee Supreme Court said, "We conclude that the preembryos are not, strictly speaking, either 'persons' or 'property' but occupy an interim category that entitles them to special respect because of their potential for human life."

This respect and protection can be shown in two ways. First, by limiting the time in which extracorporeal pre-embryos can be used, whether in research or for conception. Most commissions have chosen 14 days after fertilization as a cut-off, since that is when the primitive streak appears. Second, by insisting that the uses to which pre-embryos are put are scientifically or medically significant, and not frivolous.

Dispositional disputes are difficult to resolve because often the procreative interests of both parties are at stake.<sup>4</sup> Robertson has argued that the desire to avoid reproduction should take priority, so long as the party wishing to reproduce could, without undue burden, create other embryos (Robertson, 1989, p. 9). This balancing approach seems fair, so long as the physical, emotional, and financial burdens and risks to women who undergo IVF are not underestimated. "The crucial point is that the relevant interests are not those of the embryos but those of the disputing parties. These cases will rarely be easy to resolve, but without conceptual clarity about the nature and status of extracorporeal embryos, they will be hopeless" (Steinbock, 1992, p. 219).

## Notes

1. Screening for cystic fibrosis has turned out to be more complicated than researchers thought. In 1989, when the gene for cystic fibrosis was isolated, some scientists thought prenatal diagnosis was around the corner. However, biologists have found more than 350 points at which the gene can be mutated, and more are appearing all the time. With so many possible mutations, the potential combinations in a person who inherits one gene from each parent are endless. Researchers are also finding that combinations of different mutations produce different effects. Some cause cystic fibrosis, but others cause less serious disorders, like infertility, asthma, or chronic bronchitis. Norman Fost, a pediatrician and ethicist at the University of Wisconsin, says that the cystic fibrosis research shows that "there is, in fact, no such thing as a single-gene genetic disorder." (Gina Kolata, "Cystic Fibrosis Surprise: Genetic Screening Falters," *The New York Times*, November 11, 1993, C1.)
2. Someone who takes the third position will not agree with Mary Anne Warren that abortion is "morally neutral," comparable to having one's hair cut (Warren, 1973, 1984, p. 109). The third position is consistent with the interest view, which allows that non-interested beings can have moral value, though not moral status (Steinbock, 1992, p. 166).
3. A side issue which space prevents me from addressing is whether fertility centers should provide treatment for women who are post-menopausal, and therefore need another woman's eggs to establish a pregnancy. See William E. Schmidt, "Birth to 59-Year-Old Raises British Ethical Storm," *The New York Times*, December 30, 1993, A1.
4. In fact, Mrs. Stowe's procreative interests were not at stake ultimately in this case, because she no longer wanted to have the embryos implanted in her uterus, but rather to donate them to another infertile couple. Her reproductive liberty is not implicated in her desire to have her genetic offspring brought to birth by someone else, who will become the rearing parent.

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# **Cross-Cultural Analysis of Policies Regarding Embryo Research**

by

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Developing policy in the area of embryo research is very complex because of the myriad of factors involved. Many sensitive issues must be reconciled or at a minimum, considered, before any policy on embryo research can be developed, let alone implemented. Because of the complexity of this field, and the relation of policy in this area to many other societal values, diverse approaches have been taken internationally to this issue. “Although the questions that arise with respect to law, medicine and bioethics are similar all over the world, there are differences of a philosophical, economic, social, political, religious and even geographical nature which are not easily bridged.”<sup>1</sup>

This paper analyzes the policy responses made to the issues raised by embryo research in eleven countries—Australia (Victoria), Austria, Canada, Denmark, France, Germany, Norway, Spain, Sweden, Switzerland and the United Kingdom. The similarities and differences among these approaches are highlighted.

## **Overview**

The factors to be considered in comparing the varied policies will be: the precursors to the development of policy, the extent to which embryo research is permissible, prohibitions imposed with regard to the use of embryos, limitations imposed on permissible research, and the existence of a regulatory body to authorize and oversee embryo research. Unlike the United States, where laws affecting embryo research are generally part of legislation affecting abortion and fetal research, the laws in other countries affecting embryo research are generally part of a comprehensive regulatory scheme addressing *in vitro* fertilization and new reproductive technologies.

## **Precursors to Policy**

Each of the countries surveyed is a democratic society. However, the social and cultural diversity of these countries is reflected by a range of views on how various issues should be addressed

by public policy. To draft legislation without contemplating the divergent opinions on the issue sought to be legislated would not be an accurate reflection of the democratic process. As such, before legislation is drafted on issues as controversial as reproductive technologies and embryo research, some assessment of the various positions and concerns must be made.

All eleven countries undertook a preliminary review of the ethical and legal issues raised by new reproductive technologies before drafting or enacting legislation. In each country, legislative response was preceded by a study or report issued by an existing or newly created national commission, government agency and/or other interest group.

In Switzerland, a referendum on public demand suggested that a constitutional amendment be enacted to address the issues raised by assisted procreation.<sup>2</sup> In response to this public call, the Swiss government formed a commission to study the issues raised by genetics and new reproductive technologies.<sup>3</sup> And, in 1992 a constitutional amendment was enacted restricting the uses of assisted procreative technologies.<sup>4</sup>

The demands for public discussion and for the development of policy from interest groups, professional groups and academia were the impetus for the Canadian government's appointment of the Royal Commission on New Reproductive Technologies.<sup>5</sup> The Commission was composed of five women with backgrounds in medicine, philosophy, religion and education. The Commission was to consider and issue recommendations on new reproductive technologies. To accomplish this, the Commission held public hearings, set up a toll-free number which individuals could call to express their views, and conducted surveys of opinion.<sup>6</sup>

To fulfill their mandate, the Commission sought ways to "consult with Canadians from all sectors of society and listen to their views and experiences on the issues surrounding new reproductive technologies".<sup>7</sup> In formulating its recommendations, the Royal Commission tried to accommodate the perspectives of individuals, interest groups, professional organizations and the community at large. The views of these individuals, groups and organizations were taken into account by the Commission in issuing its final recommendations enabling the Commission to "recommend a comprehensive approach to the technologies that recognizes and accommodates the dynamic nature of society and technology and the interaction between them."<sup>8</sup> The resulting 293 recommendations and accompanying explanatory text were submitted to the Canadian government on November 15, 1993. There has not yet been enough time for a legislative response.

In Victoria, Australia, in response to the rapidly developing technologies of assisted reproduction, highlighted by the birth of Victoria's first *in vitro* baby, the third such baby in the world, a committee was appointed by the government to assess the social, ethical and legal issues resulting from *in vitro* fertilization.<sup>9</sup>

The committee was composed of a professor of law, a priest, a former teacher with an interest in migrant welfare and education, a Christian ethicist, two professors of medicine, a social worker, a physician and a legal practitioner.<sup>10</sup> The multidisciplinary, socially diverse, four-female, five-male composition of the committee is illustrative of the "government's perception that the issues involved [with *in vitro* fertilization procedures] required varied perspectives for their resolution."<sup>11</sup> The committee was asked to:

consider whether the community and the parties (that is, the donors, the embryo, and the medical and scientific personnel) involved in the process of IVF have any rights and/or obligations and, if so, whether such rights and/or obligations should be enforced, in legislative form or otherwise.<sup>12</sup>

As in Switzerland and Canada, the views of the public were an important component to policy-making in Victoria, Australia. The Committee used newspaper advertisements to invite members of the public to submit their views on the disposition of embryos.<sup>13</sup> In addition to these submissions, the committee also considered the response of individuals invited to attend committee meetings who had expertise or special interest in the issues related to embryo disposition.<sup>14</sup>

The expertise and views of the committee members combined with the expertise and views of members of the community at large resulted in the issuance of recommendations which formed the basis for the Infertility (Medical Procedures) Act 1984.

These three examples illustrate the significant role of the community in the formulation of policy concerning new reproductive technologies. Because the field of reproductive technology raises not only legal but also moral or ethical questions, divergent opinions abound. By considering the community responses which will likely reflect the moral positions, formulating an enforceable law will be facilitated because the parameters of what the community finds acceptable or unacceptable can be assessed and then incorporated into policy. This approach reflects the view that "[t]he law is not really concerned with the enforcement of morality but rather with providing a framework of peace and order within which people may exercise their moral choices and engage in what John Stuart Mill calls their own 'experiments in living'."<sup>15</sup> Community input helps to frame these bounds.

## Permissibility of Embryo Research

Although all eleven countries surveyed undertook some form of preliminary review of the legal and ethical implications of new reproductive technologies, and all allow *in vitro* fertilization, the countries do not all agree about the permissibility of embryo research and various related technologies. Of the countries surveyed, one prohibits outright all research utilizing embryos;<sup>16</sup> six allow some research but under very limited circumstances;<sup>17</sup> and four liberally permit research on embryos.<sup>18</sup>

Most of the countries surveyed do not specifically address particular technologies that involve the use of embryos (such as twinning, preimplantation genetic screening, *in vitro* fertilization experimental technologies, gene therapy, cryopreservation and basic scientific research). However, inferences about the acceptability of certain procedures can be made from the context of the legislation and the general rule on uses of embryos. Four of the countries surveyed allow twinning;<sup>19</sup> six permit preimplantation genetic screening;<sup>20</sup> all countries surveyed, except Norway, allow *in vitro* fertilization experimental techniques;<sup>21</sup> only four countries seem to permit gene therapy;<sup>22</sup> all of the countries except Switzerland allow cryopreservation<sup>23</sup> and five seem to permit basic scientific research.<sup>24</sup>

The legislation in Norway, the only country surveyed to completely prohibit research on embryos, is directed toward regulating two types of artificial fertilization: artificial insemination and fertilization outside the body.<sup>25</sup> Fertilization outside the body, the fertilization procedure most relevant to embryo research, is only permitted when the woman is sterile.<sup>26</sup> The fertilized eggs

resulting from the procedure may only be used for implantation; “[r]esearch on fertilized eggs is prohibited”.<sup>27</sup> The combined effect of these limitations is to prohibit both therapeutic and non-therapeutic procedures involving embryos, including twinning, preimplantation screening, gene therapy and techniques to improve *in vitro* fertilization procedures.

Canada, a country which is quite liberal in its proposed regulation of research utilizing embryos, not only supports allowing research on embryos but encourages it as “an important component of the ethical provision of IVF and related techniques of assisted conception”.<sup>28</sup> In drafting its recommendations, the Royal Commission on New Reproductive Technologies acknowledged the need for developing preimplantation diagnostic techniques and improving *in vitro* fertilization and cryopreservation techniques. Each of these techniques would necessarily involve performing research on embryos. In addition, the recommendations also leave open the possibility of utilizing embryos for basic scientific research if “[t]he objective of research on human zygotes should be achievable only through the use of human zygotes”.<sup>29</sup>

Although the recommendations in Canada liberally permit research on embryos, not all experimental techniques are permitted.<sup>30</sup> The Commission comments that the technique of twinning is ethically unacceptable and antithetical to respect for human life and dignity.<sup>31</sup> Additionally, gene therapy on embryos is not recommended<sup>32</sup> due to the Commission’s belief that the risks outweigh the benefits and the availability of other means to avoid passing on genetic disorders.<sup>33</sup>

Switzerland, in contrast, has a very restrictive policy on embryo research. The law in Switzerland prohibits the use of assisted procreation techniques for research purposes,<sup>34</sup> and further, restricts the use of assisted procreation techniques to situations involving sterility or a risk of transmitting a serious disease.<sup>35</sup> The language of the legislation would seem to prohibit all research, but consideration of the purpose of the legislation—to protect individuals from the potential abuses of genetics and assisted procreation techniques<sup>36</sup>—suggests that *in vitro* fertilization experimental procedures would be permitted. Such research may enable a couple to procreate when they otherwise could not. In addition, if *in vitro* fertilization is to be practiced some research would be necessary to prevent the abuses the law was designed to address.

The different approaches to regulating embryo research taken by the countries illustrate the varied views on the acceptability of the practice. Not only do individuals within a given community disagree about the limitations that should be imposed on embryo research, but the policy-making bodies of different countries have taken differing approaches as well.

## **Prohibitions Imposed With Regard to the Utilization of Embryos**

Despite the lack of consensus among the countries on the permissibility of twinning, preimplantation genetic screening, *in vitro* fertilization experimental procedures, gene therapy, cryopreservation and basic scientific research, there is some agreement about procedures which should be prohibited. The reason for this consensus among the countries is that there are common fears among individuals about the possibilities inherent in the development of new reproductive technologies. A statement by a commentator describing the situation in the United Kingdom before enactment of the Human Fertilization and Embryology Act seems to be representative of the climate in the other countries surveyed. He wrote:

It became clear...that there was strong public anxiety at the thought of scientists being completely uncontrolled in particular fields of endeavor. Stories of hybrids, mutants, clones, monsters, are the staple of horror science fiction; only strict control could keep them from becoming science fact.<sup>37</sup>

Allaying these fears appears to have been one of the purposes of developing policy in the field of new reproductive technology. Six countries explicitly ban cloning.<sup>38</sup> Because of their more restrictive policies on embryo utilization, Austria, France, Norway, Sweden and Switzerland, while not explicitly banning cloning, presumably do so.<sup>39</sup> Creation of chimeras and hybrids is also widely prohibited, as six countries have explicitly banned the procedure.<sup>40</sup> Since those countries imposing an explicit ban include the countries taking the most liberal stance on the use of embryos, it may be presumed that the other five countries, adopting more restrictive approaches, ban these procedures as well.<sup>41</sup>

Other expressly prohibited activities include cross-species implantation which five countries expressly ban;<sup>42</sup> and sex selection for reasons other than preventing transmission of a sex-linked disorder which is expressly prohibited by three countries.<sup>43</sup> Although these procedures are not expressly prohibited by the other countries they would impliedly be banned. Additionally, some countries prohibit commercial use of embryos.<sup>44</sup>

The express and implied prohibitions reveal that there is more agreement concerning what procedures to prohibit than there is regarding what procedures to permit. In allowing certain procedures, the countries are much less definitive than they are with regard to prohibitions.

## **Limitations Imposed on Permissible Research**

Placing limitations on permissible research is another area where there is some consensus among the countries. Even those countries taking the most liberal stance on embryo research have imposed boundaries within which such research must be conducted in order to be permissible. These limitations are in part a response to the moral dilemmas posed by utilizing embryos for research purposes. As one commentator has noted, "rules and policies about how embryo research should occur can symbolize respect for human life.... Policies about embryo transfer, purpose, time limits and source can amply demonstrate the embryo's special status without incurring the costs to others that arise when all research with nontransferred embryos is banned."<sup>45</sup> Essentially, limitations reflect a compromise between the acceptability and unacceptability of embryo research.

Some of the restrictions adopted by particular countries include: requiring informed consent of progenitors or donors, restricting research to the period of time when the primitive streak appears in the embryo,<sup>46</sup> requiring research to occur at an authorized site and requiring a license or some type of advance review of the research protocol or procedure sought to be implemented.

Nine of the eleven countries surveyed require informed consent.<sup>47</sup> Seven of those countries specifically required informed consent for use of embryos in research.<sup>48</sup> These countries require that the progenitors or donors of gametes be informed about how an embryo created from their gametes will be utilized.

Even if a country's law does not specifically address informed consent to embryo research, there is generally a requirement that informed consent be given in advance of *in vitro* fertilization.

At least two countries that do not have a provision for consent to research have a provision for consent to *in vitro* fertilization.<sup>49</sup> For example, in Germany a penalty of up to three years' imprisonment or a fine is imposed on a person who "attempts to artificially fertilize an egg cell without the woman whose egg cell is to be fertilized, and the man whose sperm cell is to be used for fertilization, having given consent."<sup>50</sup> Canada is one country that specifically requires informed consent for research. Recommendation 186 of the Royal Commission on New Reproductive Technologies' report suggests that:

Clinics and researchers be permitted to use human zygotes for research only with the fully informed consent of the persons who have donated the gametes used to create the zygote.<sup>51</sup>

Six countries restrict research to the first 14 days after fertilization before the appearance of the primitive streak.<sup>52</sup> This requirement is believed to reflect respect for the status of the embryo. The appearance of the primitive streak is thought to be the point at which the individuality of the embryo is settled.<sup>53</sup> The reason for this is that this is the last point at which twinning or higher-order identical multiple births may result from the embryo splitting and at which two embryos can fuse to form a single embryo.<sup>54</sup> Development of the primitive streak is also the precursor to the nervous system, suggesting that this is the point beyond which the embryo will become sentient.<sup>55</sup>

Six countries require that the performance of research on embryos, or other procedures involving embryos, occur at an authorized site.<sup>56</sup> This limitation helps to ensure that the conditions under which *in vitro* fertilization and/or research occurs are safe. Other safety requirements include requiring that research and/or *in vitro* fertilization procedures be performed by an authorized practitioner.<sup>57</sup>

Some aspects of the countries' laws focus on the interests of the embryo, while others focus on the interests of the progenitors. These two sets of interests may come into conflict as evidenced in the context of *in vitro* fertilization experimental procedures.

Improvement of existing techniques needs to be distinguished from the development of new techniques for creating embryos... In the latter cases destructive embryo research is more likely necessary... When attention is turned to research to improve or develop IVF techniques... the woman is frequently lost sight of as the subject of research.<sup>58</sup>

Limitations on the use of embryos provide guidance to confront these potential conflicts.

Another significant restriction is the requirement that a license or some type of authorization be obtained before research can be carried out. This is required in six of the countries surveyed.<sup>59</sup> The importance of this restriction will be discussed below in the Section entitled "The Existence of a Regulatory Body."

## **The Existence of a Regulatory Body**

Reproductive technology is developing rapidly and with each new development new legal, ethical and social issues arise.<sup>60</sup> How can the law keep pace with such a dynamic force? The credibility of the law depends, in part on its stability, yet the constant changes in new reproductive technologies require a great deal of flexibility, adaptability, and technical understanding in the law. One way in which legislation can accommodate the dynamic nature of science and the questions new

technologies raise would be to set general bounds and appoint a regulatory body to address specific issues as they arise.

The advantage of leaving the development of principles to the regulatory body is that this will consist of a body of experts drawn from different disciplines so that decisionmaking should result from the interplay of different knowledge bases and ethical positions. It has expertise and experience which a legislature lacks.<sup>61</sup>

Of the eleven countries surveyed, seven make specific mention of a regulatory body.<sup>62</sup> The number of members of the committees differs in each country but generally the composition is multidisciplinary. For example, in Australia, the Standing Review and Advisory Committee must consist of eight members: an individual qualified in the study of philosophy, two medical practitioners, two representatives from the religious community, a social worker, a legal practitioner and a teacher with an interest in community affairs.<sup>63</sup> In France, one component of the National Consultative Commission on Ethics for Life Sciences and Medicine must include persons "belonging to the principal philosophical and spiritual families."<sup>64</sup>

The regulatory bodies in the seven countries are responsible for authorizing or licensing various activities involving embryos and new reproductive technology. The most elaborate licensing scheme is that described in the Human Fertilization and Embryology Act 1990 of the United Kingdom. The Act provides that:

1. No person shall—
  - (a) bring about the creation of an embryo, or
  - (b) keep or use an embryo, except in pursuance of a license.<sup>65</sup>

In the United Kingdom, the Human Fertilization and Embryology Authority (the Authority) is responsible for maintaining one or more committees to carry out its functions related to granting, varying, suspending and revoking licenses.<sup>66</sup> Three types of licenses are regulated by the Authority: licenses for treatment, for storage and for research.<sup>67</sup> The law lays down several conditions which must be met in order for the Authority to grant a license under each category.<sup>68</sup> To authorize activity involving embryos under a research license the Authority must find the activity to be

- necessary or desirable for the purpose of—
- (a) promoting advances in the treatment of infertility,
  - (b) increasing knowledge about the causes of congenital disease,
  - (c) increasing knowledge about the causes of miscarriages,
  - (d) developing more effective techniques of contraception, or
  - (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,
- or for such other purposes as may be specified on regulations.<sup>69</sup>

The Act sets out the bounds of the law and the Authority makes the law operational. Determining if an activity fits within one of these categories depends on the discretion of the licensing committee which is directed by its multidisciplinary composition. The licensing requirement of the Act not only functions as a way to monitor research procedures, it also injects flexibility into the law so the law can adapt to new technologies. Technologies not foreseen at the time of the legislative enactment are still susceptible to regulation in that if they are to be performed, they must be submitted to the licensing authority.

The Canadian Royal Commission on New Reproductive Technologies, recognizing the need for regulation of the field of new reproductive technology for flexibility of the law, recommends formation of a National Reproductive Technologies Commission.<sup>70</sup>

In summarizing their recommendations, the Canadian Royal Commission acknowledges that, criminal legislation is not flexible enough to regulate the day-to-day provision of new reproductive technologies. To ensure that new reproductive technologies are provided in a safe, ethical, and accountable way within these boundaries, [the Commission] recommend[s] that the federal government establish an independent National Reproductive Technology Commission...<sup>71</sup>

The Canadian Commission is to be composed in such a way as to reflect various perspectives, to represent a broad range of interests, and several areas of expertise.<sup>72</sup> It is recommended that the Commission's diversity mirror the diversity of the Canadian populace.<sup>73</sup> Because of the many facets of reproductive technology, it is recommended that the National Commission establish six sub-committees focusing on infertility prevention; assisted conception; assisted insemination; prenatal diagnosis and genetics; human zygote/embryo research; and fetal tissue for use in research.<sup>74</sup> Directives are recommended for each sub-committee.

The Canadian Royal Commission recommends that the Embryo Research Sub-Committee license facilities where research on embryos is performed, develop guidelines and standards to be adopted as requirements for issuance of a license and monitor developments in the field of embryo research.<sup>75</sup> The Canadian Royal Commission suggests general regulations and recommends that specific regulation be the province of specialized committees like the Embryo Research Committee overseen by the National Commission.

The need for regulation is acknowledged by the countries surveyed, but it can be difficult to determine in advance the full range of appropriate regulations when the subject to be regulated has numerous applications and is constantly raising new ethical, social, philosophical and medical questions with each new development. The method chosen by most of the countries to address this has been the creation of a multidisciplinary committee to authorize and oversee activities attendant to new reproductive technologies. The composition of the committees may be viewed as a microcosm of the community in which they operate as is the composition the Canadian Royal Commission recommends.<sup>76</sup> Therefore, with each new development, varying views can be taken into account when determining the permissibility of certain activities.

In the past in the United States in the area of biomedicine, there has been a reluctance to delegate much authority to a specialized commission. For example, with respect to state-sponsored newborn screening, only a few states created Hereditary Disease Commissions to assess new technologies and determine which tests should be added to the list of state programs. The vast majority of states relied on the legislative process and adopted laws detailing the specific types of tests that should be undertaken. This probably reflects the view in the United States that acting in the legislative context is the most appropriate way to assure input from various members of the community and to assure that policy is not adopted without open public discussion.



## Conclusion

The issue of embryo research is very controversial, as is illustrated by the different approaches to regulation taken by the eleven countries surveyed. Each country developed its regulatory scheme pursuant to a study or report by a national commission or government agency examining the social, legal and/or ethical issues raised by new reproductive technologies. Although considering many of the same issues, the resultant policy differs from country to country. Such diversity, however, is not surprising considering the differing social, ethical and religious culture of the countries.

The level of acceptability of embryo research is varied, but consensus does exist regarding the types of activities to be prohibited. The policies analyzed indicate agreement that certain techniques—cloning, inter-species fertilization and the creation of chimeras should be prohibited. There is also agreement that if research is permissible, limitations are necessary; the degree of limitation, though, does differ. The policies establish general limitations, but have delegated responsibility for issuing specific regulations to a regulatory body.

The policies reviewed provide the framework in which embryo research is permissible—generalities about the types of acceptable activity and prohibitions—but details are left to be determined by a regulatory body. In this way, the particular implications of an activity can be assessed factoring in the state of knowledge at that time and the degree of acceptability of the proposed procedure within the community. It is the factor of community acceptance which gives rise to the difference in approaches. Diverse ethical, philosophical, social and religious views have been considered by the various nations and accommodated in an attempt to develop the most effective, workable policy.

## Notes

1. Morgan, D. and Nielsen, L., "Prisoners of Progress or Hostages to fortune?" in *Journal of Law, Medicine & Ethics* 21(1); 30-42: Spring, 1993.
2. OTA, *Infertility: Medical and Social Choices*, "Appendix E: International Developments" p. 346 (May, 1988).
3. *Id.*
4. 24 *novies*.
5. See Royal Commission on New Reproductive Technologies, *Proceed With Care*, 1993 at 1-2.
6. *Id.* at xxxi.
7. *Id.* at 8
8. *Id.*

9. Gaze, B; and Kasimba, P. "Embryo Experimentation: The Path and Problems of Legislation in Victoria," in *Embryo Experimentation*, eds. Singer, P.; Kuhse, H.; Buckle, S.; Dawson, K.; and Kasimba, P., Cambridge University Press, 1990).
10. Waller Committee Report on the Disposition of Embryos Produced by In Vitro Fertilization, p. 1 (1984).
11. Gaze, B. and Kasimba, P., *supra* note 9 at 206.
12. *Supra note* 10 at 2.
13. *Id.* at 4-5
14. *Id.* at 5
15. Charlesworth, M. "Community Control of IVF and Embryo Experimentation" in *Embryo Experimentation* at 149, eds. Singer, P., et, al.
16. Norway, Law No. 68 of 12 June, 1987.
17. Australia, Infertility (Medical Procedures) Act, 1984; Austria, Law No. 275; Denmark, Law No. 503 of 24 June, 1992; France, Art. L. 672-7; Germany, the Embryo Protection Law and Switzerland, 24 *novies* which is an amendment to the Constitution of Switzerland.
18. Canada, *Proceed With Care* p.p. 607-659; Spain, Law No. 35/1988 and Law No. 42/1988; Sweden Law No. 115; and the United Kingdom, The Human Fertilization and Embryology Act 1990.
19. Australia, Infertility (Medical Procedures) Act; France, Art. L. 671-2; Sweden, Law No. 115; United Kingdom, Human Fertilization and Embryology Act 1990.
20. Canada, *Proceed With Care*; Denmark, Law No. 503; France, Art. L.673-6; Spain, Law No. 35/1988; Sweden, Law No. 115; and United Kingdom, Human Fertilization and Embryology Act, 1990).
21. Norway, Law No. 68.
22. France, Art. L.673-6; Spain, Law No. 35/1988; Sweden, Law No. 115; and United Kingdom, Human Fertilization and Embryology Act 1990.
23. Switzerland, 24 *novies*.
24. Canada, *Proceed With Care*; France, Art. L. 671-2 bis; Spain, Law No. 35/1988; Sweden, Law No. 115; and United Kingdom, Human Fertilization and Embryology Act 1990.
25. Law No. 68, Sec. 1.
26. Law No. 68, Sec. 12.

27. Law No. 68, Sec. 3.
28. *Proceed With Care* at 651.
29. *Proceed With Care*, Rec. 198 (h) p. 648.
30. There are explicit prohibitions in the recommendations which will be addressed in a later section.
31. *Proceed With Care* p. 741.
32. *See Proceed With Care* Rec. 185 at p. 638.
33. *See Proceed With Care* p.p. 637-638.
34. 24 *novies*, Sec. 2 (c).
35. 24 *novies*, Sec. 2 (c).
36. 24 *novies*, Sec. 1.
37. McK. Norrie, K., "United Kingdom: Legal Regulation of Human Reproduction", 201-222 in *Law Reform and Human Reproduction*, ed. McLean, S.A., Dartmouth Publishing, 1992.
38. Australia, Infertility (Medical Procedures) Act 1984; Canada, *Proceed With Care*; Denmark, Law No. 503; Germany, the Embryo Protection Law; Spain, Law No. 35/1988; United Kingdom, Human Fertilization and Embryology Act 1990.
39. Austria, Law No. 275; France, Art. L. 673-6; Norway, Law No. 68; Sweden, Law No. 115 and Switzerland, 24 *novies*.
40. Australia, Infertility (Medical Procedures) Act 1984; Canada *Proceed With Care*; Denmark, Law No. 503; Germany, Embryo Protection Law; Spain, Law No. 35/1988; and United Kingdom, Human Fertilization and Embryology Act 1990; also *see* Austria, Law No. 275; Norway, Law No. 68 which prohibits all research; Sweden, Law No. 115 and Switzerland, 24 *novies*.
41. Austria, Law No. 275; France, Art. L. 671-2 bis; Norway, Law No. 68; Sweden, Law No. 115; and Switzerland, 24 *novies*.
42. Canada, *Proceed With Care*; Denmark, Law No. 503; Germany, Embryo Protection Law; Spain, Law No. 35/1988; and United Kingdom, Human Fertilization and Embryology Act 1990.
43. Canada, *Proceed With Care*; Germany, Embryo Protection Law; and Spain, Law No. 35/1988.
44. *See e.g.* France, Art. L. 671-2 which reads that: "Commercial and industrial use of embryos is prohibited." The legislation penalizes attempting or attempting to obtain embryos for payment (Art. L. 682-3).

45. Robertson, J. "Embryo Research," 24 *University of Western Ontario Law Review* 15-37 at 27 (1986).
46. The primitive streak is generally believed to appear 14-15 days after fertilization. See, e.g. Morgan, D. & Lee, R., *Blackstone's Guide to the Human Fertilization and Embryology Act 1990* at xiii, Blackstone Press, Ltd., 1991.
47. Australia, Infertility (Medical Procedures) Act, 1984; Austria, Law No. 275; Canada, *Proceed With Care*; Denmark, Law No. 503; France, Art. L. 671-3; Germany, Embryo Protection Law; Spain, Law No. 35/1988 and Law no. 42/1988; Sweden, Law No. 711; and United Kingdom, Human Fertilization and Embryology Act 1990.
48. Australia, Infertility (Medical Procedures) Act 1984; Canada, *Proceed With Care*; Denmark, Law No. 503; France, Art. L. 671-2 bis; Spain, Law No. 35/1988 and Law No. 42/1988; Sweden, Law No. 115; and the United Kingdom, Human Fertilization and Embryology Act 1990.
49. Austria, Law No. 275; Germany, Embryo Protection Law.
50. Embryo Protection Law, Sec. 4(1)(1).
51. *Proceed With Care* at 639; also see United Kingdom, Human Fertilization and Embryology Act, Schedule 3 and Spain, Law No. 35/1988, Sec. 15(1)(a) and Law No. 42/1988, Sec. 2(b).
52. Australia, Infertility (Medical Procedures) Act 1984; Canada, *Proceed With Care*; Denmark, Law No. 503; Spain Law No. 35/1988; Sweden, Law No. 115 and United Kingdom, Human Fertilization and Embryology Act 1990.
53. See, Dawson, K., "Segmentation and Moral Status: A Scientific Perspective" at p. 58 in *Embryo Experimentation*, eds., Singer, P., et al., Cambridge University Press, 1990.
54. *Id.*
55. Robertson, *supra* note 44 at 25.
56. See Australia, Infertility (Medical Procedures) Act 1984, Secs.; Austria, Law No. 275; Canada, *Proceed With Care*; France, Art. L. 673-1; Spain, Law No. 35/1988 and Law No. 42/1988 and United Kingdom, Human Fertilization and Embryology Act 1990. Although this requirement may not be mentioned in some of the statutes reviewed, it cannot be assumed that it is not required as other legislation not reviewed may be applicable.
57. See Austria, Law No. 275; Canada, *Proceed With Care*; France, Art. L. 673-6; Germany, Embryo Protection Law; Spain Law No. 35/1988 and Law No. 42/1988; and United Kingdom, Human Fertilization and Embryology Act 1990. Although this requirement may not be mentioned in some of the statutes reviewed, it cannot be assumed that it is not required as other legislation not reviewed may be applicable.
58. Gaze, B., and Dawson, K., "Who is the Subject of Research?" in *Embryo Experimentation*, at pp. 120-121, eds Singer, P., et al., Cambridge University Press, 1990.

59. See Table I.
60. For example, while this paper was being prepared, a new issue arose in Great Britain. Infertility researchers there proposed to take eggs from aborted fetuses and donate them to infertile women. The issue is currently before the Human Fertilization and Embryology Authority. See, e.g. Lawrence Donegan and John Ezard, "Opposition Grows to Use of Eggs from Foetuses," *The Guardian* 2 (January 4, 1994); David Fletcher, "BMA to back New Fertility Technique," *The Daily Telegraph* 1 (January 3, 1994); and William Touhy, "Use of Fetal Eggs for Fertility Sparks Furor," *Los Angeles Times* A1, Col. 5 (January 3, 1994).
61. Freeman, M., "Responding to the Reproductive Revolution: Law Reform — Dilemmas and Difficulties," pp. 3-16 at 11 in *Law Reform and Human Reproduction*, ed. McLean, S.A., Dartmouth Publishing, 1992.
62. Australia, Infertility (Medical Procedures) Act 1984, Sec. 29; Canada, *Proceed With Care*, Rec. 1; Denmark, Law No. 503, Sec. 14; France, Art. L. 673-6; Spain, Law No. 35/1988 Sec. 21 and Law No. 42/1988, Additional Provisions Sec. 1(f); Sweden, Law No. 115 Sec. 3,5, and 7 which refers to the National Board of Health and Welfare as having authority over the storage of fertilized oocytes but does not specifically mention authority over research; and the United Kingdom, The Human Fertilization and Embryology Act 1990 Sec. 5.
63. Australia, Infertility (Medical Procedures Act) 1984, Sec. 29(1)(a)-(f).
64. France, Article I A.
65. Human Fertilization and Embryology Act 1990, Sec. 3(1).
66. Human Fertilization and Embryology Act Sec. 9(1).
67. Human Fertilization and Embryology Authority Sec. 11.
68. Human Fertilization and Embryology Authority 1990, Schedule 2.
69. Human Fertilization and Embryology Act 1990, Schedule 2, Sec. 2.
70. Canada, *Proceed With Care*, Sec. 1.
71. *Proceed With Care*, at 1023.
72. *Id.* Also see France, Article I A describing the composition of the National Commission on Ethics For Life Sciences and Medicine as another example of a committee composition reflecting various perspectives.
73. *Id.*
74. *Id.*

75. *Proceed With Care*, Rec. 197.

76. Canada, *Proceed With Care* at 1023 and see e.g. Australia, Infertility (Medical Procedures) act 1984, Sec. 29.

**Appendix A**

**Country-by-Country Analysis**

COUNTRY: AUSTRALIA (Victoria)

NOTE: The legislation in Victoria is currently under review. The following questions will be answered according to the existing laws, as amended in 1987.

I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP? Yes, several reports were compiled by a committee appointed by the government. The committee was formed to study the social, ethical and legal implications of in vitro fertilization. (Gaze, B.; Kasimba, P. "Embryo Experimentation: The path and problems of legislation in Victoria," in Embryo Experimentation, eds: Singer, P.; Kuhse, H.; Buckle, S.; Dawson, K.; Kasimba, P., Cambridge University Press (1990)). The committee, headed by Louis Waller, the current chair of the Standing Review and Advisory Committee, was known as the Waller Committee. The Committee issued three reports which came to be the foundation of the Infertility (Medical Procedures) Act. The first report, the *Interim Report*, focused on background information regarding the development of in vitro fertilization (*id.* at 205). The second report, the *Report on Donor Gametes in IVF*, addressed the acceptability of use of donor gametes, the parental rights issues raised by use of donor gametes and what donor information should be



disclosed to recipients (*id.* at 206). The final report, *Disposition of Embryos Produced by In Vitro Fertilization*, addressed the issues of cryopreservation of embryos, embryo research in an in vitro fertilization program, surrogacy arrangements and future supervision of the field of reproductive technology. (*Report on the Disposition of Embryos Produced by In Vitro Fertilization, 1984*) Many of the recommendations made in these three reports were incorporated into the Infertility (Medical Procedures) Act 1984.

II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes, the Infertility (Medical Procedures) Act 1984. This Act provides comprehensive regulation of the field of in vitro fertilization. The focus on in vitro fertilization is apparent from the definition of "approved experimental procedure" which "means an experimental procedure directly related to the alleviation of infertility. . ." (sec.3(1)). Such procedures are subject to review and approval by the Standing Review and Advisory Committee (see, secs.3(1) and 29). The rule provides that research that would damage the embryo, make it unfit for implantation or reduce the prospects of pregnancy resulting from implantation is not permissible unless it is related to the alleviation of infertility.

The Act permits experimental procedures on embryos under limited circumstances and subject to the approval of the Standing Review and Advisory Committee, discussed infra at IV. (sec. 6) Such experimentation must be related to the alleviation of infertility. (sec. 3(1))

Presently, though, the legislation is under review, having been criticized for being ambiguous; and a moratorium is in effect which bans research on embryos beyond 22 hours.

(Birnbauer, B. "Australia: Quality Control or Tragedy? The Embryo Debate Reborn," *The Age (Melbourne)*, October 22,

1993) It is expected that in rewriting the Act, the recommendations of the Standing Review and Advisory

Committee, currently headed by Louis Waller, will be

adopted. (Ryan, D. "Australia: IVF and Embryo Laws Expected to be Liberalised," *Sunday Age (Melbourne)*, June 13, 1993)

The Committee has recommended that "testing of embryos up to 14 days be allowed . . . [and] that embryos could only be

used if they would enhance the success of IVF and were

surplus to the requirements of a couple on an assisted

fertility program."(id.) These recommendations are nearly

identical to those made in the third report issued by the

Waller Committee in 1984.

#### **A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** Twinning, because it increases the chances of success of an in vitro fertilization treatment would likely be allowable under the Act.
2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?** No, preimplantation screening is not directly related to alleviating infertility. The procedure would seem to be prohibited under the law since it may damage the embryo. This position, however, may change if new recommendations of the Standing Review and Advisory Committee which propose that embryo biopsy be permitted if the parent has a disease which could be passed on to the child are adopted (Ryan, D., "Australia: IVF and Embryo Laws to be Liberalised," Sunday Age (Melbourne), June 13, 1993)
3. **IVF EXPERIMENTAL TECHNIQUES?** Yes, the Act permits experimentation if it is related to the alleviation of infertility (sec.3(1)), and research on the process of fertilization before syngamy (defined at III B.)(sec. 9A).
4. **GENE THERAPY FOR EMBRYOS?** No, because the technique is not for the purpose of alleviating

infertility, it is not likely to be permissible. If, however, the recommendations of the Standing Review and Advisory Committee mentioned above at 2 are adopted, gene therapy may be permitted if approved by the SRACI. The SRACI sponsored a symposium on embryo experimentation and future developments including gene therapy indicating that the Committee has some interest in the procedure. (Waller, L. "Australia: The Law and Infertility - The Victorian Experience" in Law Reform and Human Reproduction, ed. S. McLean, Dartmouth Publishing, 1992)

5. **CRYOPRESERVATION?** Yes, Section 7 and Section 8 permit ova and embryo freezing. The Waller Committee in its third report, had recommended that research on ovum freezing should be encouraged in order to reduce the need to freeze embryos (Third Report, Waller Committee sec. 6.5). However, in order to perfect the technique, though, an embryo resulting from a frozen ovum would need to be studied. Such a study was presented to the SRACI, and the Committee found that sec.6(5) prohibited the procedure "since it clearly involved the intentional formation of embryos which were to be damaged or destroyed in

the process of chromosomal analysis" (Law Reform and Human Reproduction p.26).

6. **BASIC SCIENTIFIC RESEARCH?** No. Because basic scientific research is not directed at improving in vitro fertilization or alleviating infertility, it is not likely that the Standing Review and Advisory Committee would approve the use of embryos in experiments to increase general scientific knowledge (see, sec.3(1) and sec.29).

**B. ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?**

Yes, cloning and cross-species fertilization are specifically prohibited (sec.6(2)(a)-(b)).

**III. DOES THE LEGISLATION DEFINE:**

- A. "EMBRYO"?** No mention.

- B. "EXPERIMENTATION" AND/OR "RESEARCH"?** Yes,  
"experimental procedure" is defined as:

a procedure that involves carrying out research on an embryo of a kind that would cause damage to the embryo, would make the embryo unfit for implantation or would reduce the prospects of a pregnancy resulting from the implantation of the embryo.

(sec.6(4)) The definition makes clear that an experimental procedure is one type of research. The Act does consider research on the process of fertilization before syngamy to be an experimental procedure. (sec.9A) Syngamy is defined as "the alignment of the mitotic spindle of the chromosomes derived from the pronuclei" (sec.3(1)). The legislation also defines "approved experimental procedure" as being:

an experimental procedure directly related to the alleviation of infertility and approved by the Standing Review and Advisory Committee . . .

(sec. 3(1))

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION?** Yes, the Standing Review and Advisory Committee (SRACI) (sec. 29).

**A. COMPOSITION:** The committee is a multidisciplinary team appointed by the Minister of Health. The 8 member committee must include an individual qualified in the study of philosophy, two medical practitioners, two representatives from the religious community (no requirement that a particular religion be represented is articulated), a social worker, a legal practitioner and a teacher with an interest in community affairs

(sec.29(1)(a)-(f)). A multidisciplinary committee was recommended to reflect the many interests in the community (see, *Waller Committee*, 3rd Report sec.5.5)

**B. AUTHORITY/RESPONSIBILITY:** The charge to the SRACI includes: ". . . consider[ing] requests for approval of and, if it sees fit, . . . approv[ing], experimental procedures . . ."(sec.29(6)(b)). In fulfilling its responsibility, the SRACI is given wide discretion. No specific guidelines are prescribed, directing the committee as to the factors it should consider in determining whether to grant approval of an experimental procedure other than that the procedure be directed towards alleviating infertility (see secs. 3(1) and 29(7)(a)). Generally, though, the legislation dictates that in carrying out its responsibilities, the committee:

(a) shall have regard to the principle that childless couples should be assisted in fulfilling their desire to have children;

(b) shall ensure that the highest regard is given to the principle that human life shall be preserved and protected at all times; and

(c) shall have regard to the spirit and intent of the several provisions of this Act.

(sec. 29(7)).

**C. GRIEVANCE PROCEDURE:** No mention.

NOTE: Because embryos utilized in "experimental procedures" are derived as a result of in vitro fertilization procedures (see, sec. 6(5) and sec.9A(b)(ii)), the "quality assurance mechanisms" and "requirements affecting donor/progenitor" relevant to the performance of in vitro fertilization will presumably be applicable to experimental procedures.

**V. QUALITY ASSURANCE MECHANISMS**

**A. AUTHORIZED SITE?** The Act limits the practice of in vitro fertilization to and permits the freezing of ova and embryos in approved hospitals (Singer, P., Kuhse, H., Buckle, S., Dawson, K., and Kasimba, P., "Summary of Legislation Relating to IVF," p. 238 in Embryo Experimentation, Cambridge University Press, 1990). The Act provides that in vitro fertilization "shall not be carried out at a place other than a hospital that is approved by the Minister as a place at which such procedures may be carried out" (Secs. 10(2), 11(2), 12(2) & 13(2)).

**B. AUTHORIZED PRACTITIONER?** No mention.



- C. **RECORDKEEPING?** Yes, when the SRACI approves an experimental procedure, it must report to the Minister (sec. 29(8), also see, sec.29(9)(a)(b)).

## VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR

- A. **INFORMED CONSENT?** Yes, written consent is required from a woman and her husband to use the woman's ova in a specific approved experimental procedure (sec. 9A(2)(b)(iii)) and from a donor and his spouse (if he has one) in writing to the use of his semen (sec.9A(3)(b)). In addition, the sections regulating in vitro fertilization require that "the woman and her husband each consents in writing to the carrying out of the procedure" (secs. 10(3)(b); 11(3)(b); 12(3)(b); and 13(3)(b)).

- B. **COUNSELLING?** The Act requires that the procedure of in vitro fertilization not be carried out unless the medical practitioner performing the procedure is satisfied that:

. . . the woman and her husband have received counselling, including counselling in relation to prescribed matters, from an approved counsellor; .  
. . . that an approved counsellor will be available to give further counsel to the woman and her husband after the procedure is carried out.

(Secs. 10(3)(e); 11(3)(e); 12(3)(e); and 13(3)(f)).

C. **MARITAL STATUS?** The Act limits the availability of in vitro fertilization to married women (Secs. 10(3)(a); 11(3)(a); 12(3)(a); 13(3)(a)). "Married woman" includes a woman "who is living with a man as his wife on a bona fide domestic basis although not married to him" (Sec. 4(2)(a)(i)).

## VI. **PENALTIES**

Carrying out prohibited procedures or experimental procedures not authorized by the SRACI is subject to 100 penalty units or imprisonment for 4 years (sec. 6).

Violation of section 9A, Research on the Process of Fertilisation Before Syngamy, is subject to a penalty of 25 penalty units or imprisonment for 1 year (sec. 9A).

"Penalty unit" is not defined in the legislation.

COUNTRY: AUSTRIA

I. BEFORE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT OR OTHER INTEREST GROUP? Two studies preceded the enactment of legislation in Austria. One was a national study of family policy and new reproductive technologies. (OTA, Infertility: Medical and Social Choices, "Appendix E: International Developments" p. 346 (May, 1988)). The other was a report issued by the Ministry of Science Research concerning issues of genetics and reproductive biology. (id.)

II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes, the Reproductive Medicine Law, Federal Law of 1992 (Serial No. 275). The law prohibits embryo research or any other use of embryos other than for medical procedures to induce pregnancy. Medically Assisted Procreation (MAP) is the focus of the legislation. MAP is defined as "the application of medical methods in order to induce pregnancy by means other than sexual intercourse" (International Digest of Health Legislation, 1993, 44(2);247, citing Federal Law of 1992 (serial no. 275)).

As no specific allowance of embryo research is articulated, no limitations are delineated which relate specifically to

embryo research. Section 9(1), though, (discussed supra) does indicate that no destructive research on embryos is permitted (see, Morgan, D. and Nielsen, L. at p.34).

**A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** No, since twinning is not yet a medically-accepted procedure to induce pregnancy.
2. **PREIMPLANTATION SCREENING OF EMBRYOS?** No, since preimplantation screening of embryos is not yet a medically-accepted procedure to induce pregnancy.
3. **IVF EXPERIMENTAL TECHNIQUES?** The statute states that viable cells "may be subjected to examination and treatment only if, taking into account the current state of medical science and experience, such action is necessary in order to achieve pregnancy" (sec.9(1)). Therefore, research concerning in vitro fertilization may be permissible in Austria.
4. **GENE THERAPY FOR EMBRYOS?** No, since gene therapy is not a medically-accepted procedure to induce pregnancy.

5. **CRYOPRESERVATION?** Yes, section 17(1) reads:

[s]perm and oocytes intended for use in MAP [Medically Assisted Procreation], as well as viable cells, may be stored for a period not exceeding one year.

The conditions of storage shall correspond to the current state of science and technology.

6. **BASIC SCIENTIFIC RESEARCH?** No. The legislation provides that "[v]iable cells may not be used for any purpose other than MAP [Medically Assisted Procreation]," (sec.9(1)) therefore foreclosing the possibility of utilizing embryos for any other purpose.

B. **ARE ANY TYPES OF PROCEDURES PROHIBITED?** The law prohibits interventions involving the germline (sec. 9(2)).

### III. DOES THE LEGISLATION DEFINE:

A. **"EMBRYO"?** The term used in the act is "viable cell" which is defined as meaning "fertilized oocytes and cells that have developed from such oocytes."  
(*International Digest of Health Legislation* 44(2):247).

B. "EXPERIMENTATION" AND/OR "RESEARCH"? No mention.

IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION? No mention.

A. COMPOSITION: N/A

B. AUTHORITY/RESPONSIBILITY: N/A

C. GRIEVANCE PROCEDURE: N/A

NOTE: Researchers will probably be required to meet the standard for performing MAP (Medically Assisted Procreation).

V. QUALITY ASSURANCE MECHANISMS

A. AUTHORIZED SITE? Procedures involving in vitro fertilization may only be performed in "specially licensed hospitals loosely supervised by one of the nine provincial Governor's Offices" (Morgan, D. and Nielsen, L., "Prisoners of Progress or Hostages to Fortune?" in 21(1) Journal of Law Medicine and Ethics 30-42 at 34, Spring, 1993).

B. AUTHORIZED PRACTITIONER? If research is permitted, the

only way to obtain the embryos would be through assisted conception, and under the Act, only obstetricians and gynecologists may practice such procedures (id.).

- C. **RECORDKEEPING?** Yes, detailed provisions address recordkeeping and reporting requirements (secs. 18-19).

## **VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR**

- A. **INFORMED CONSENT?** Yes, Section 8 addresses in detail the issue of consent.
- B. **COUNSELLING?** "The physician is required to, in detail, inform and advise the husband or partner of the procedure [Medically Assisted Procreation] and consequences to the woman and child" (sec. 7). "The physician is to arrange psychological counselling or psychotherapeutic care for the husband or partner, provided that the latter has no objection thereto" (sec. 7).

C. **MARITAL STATUS?** The statute provides that "MAP [Medically Assisted Procreation] is admissible only within the context of marriage or a relationship that approximates to matrimony" (sec. 2).

## **VII. PENALTIES**

Yes.



**COUNTRY: CANADA**

NOTE: The Royal Commission on New Reproductive Technologies issued a 1275 page report, Proceed With Care, in November, 1993 which is currently under review by the Canadian government. The report presents very comprehensive recommendations concerning embryo research and these recommendations are what will be outlined in the following. The legislature has not yet acted pursuant to the report.

I. **BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP?** In 1989, the Government of Canada appointed the Royal Commission on New Reproductive Technologies (Proceed With Care p. 2). The Commission was to:

. . .inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied. (Proceed With Care, p. 3, reprinting Order in Council No. P.C. 1989-2150.)

II. **IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH?** There is not currently a statute. Specific technologies are mentioned and will be discussed below. The Committee found

that:

. . . prohibiting research on human zygotes would create a situation where the health of women and their children was put at risk, because it would close off an avenue to knowledge that could contribute to the development and evaluation of safer, more effective ways of performing IVF. [They] therefore believe that research involving human zygotes not only is acceptable but is an important component of the ethical provision of IVF and related techniques of assisted conception. It is for these reasons that [they] have determined that such research should be permitted within the framework of licensing, ethical review, public accountability, and other safeguards . . . . (Proceed With Care, p. 651.)

All research involving human zygotes must be licensed by the National Reproductive Technology Commission (Proceed With Care Rec.193 p.645). Research involving transferring an experimentally manipulated zygote must be approved by a local research ethics board as well (Proceed With Care Rec.194 p.645). The Commission recommends thirteen requirements be imposed as conditions for obtaining a license (Proceed With Care Rec.198 p.647-648). These include restricting research to the first 14 days of development of the zygote (Proceed With Care Rec.198(a)); prohibiting using invasive procedures to retrieve eggs solely for forming zygotes for research (Rec.198(c)); and prohibiting the undertaking of such research for commercial gain (Rec. 198(g)).

**A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** No. Commenting on this procedure as performed in the United States, the Commission found that the

technique of zygote splitting has no foreseeable ethically acceptable application to the human situation . . . Its use in human zygotes offends respect for human life and dignity and provides no benefit that cannot be achieved in other, ethically acceptable ways. (Proceed With Care, p. 741.)

2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?**

Yes, the Commission acknowledges that at some point conducting clinical trials of new preimplantation diagnosis techniques will be necessary to develop knowledge (Proceed With Care p.641), but initially the risks of these techniques will be unknown. To minimize these risks, the Commission "believe[s] that any research that involves transferring zygotes that have been manipulated must be preceded by research on animal zygotes and embryos, as well as on human zygotes that are not subsequently transferred in the uterus . . ." (id. and see, Rec. 189).

3. **IVF EXPERIMENTAL TECHNIQUES?** Yes, in summarizing its recommendations with regard to embryo research, the Commission concluded "that the use

of human zygotes in research can be considered acceptable when that research is directed to promoting understanding of human health and disease and developing treatment" (Proceed With Care p.p. 650-651). With regard to infertility treatments the Committee expresses its long term goal as being

the creation of a system in which individuals who are infertile can be helped, where possible, to conceive, with a treatment that promises the greatest chances of success . . . in which scientists and researchers can carry out approved research to expand the boundaries of infertility treatment without harm to women. (Proceed With Care, p. 576.)

4. **GENE THERAPY FOR EMBRYOS?** No, the Commission recommends that "[r]esearch involving genetic alteration of human zygotes or embryos not be permissible" (Proceed With Care Rec.185 at p.638). Their rationale is that the risks of such a procedure greatly outweigh the benefits and "that there are safer and more appropriate ways for couples to manage the risk of passing on a genetic disorder " (Proceed With Care p.p. 637-638).
5. **CRYOPRESERVATION?** Yes, since cryopreservation techniques may be valuable in improving and

developing in vitro fertilization techniques, research on this procedure would be permitted in Canada (see Proceed With Care at 615 and 650-651).

6. **BASIC SCIENTIFIC RESEARCH?** Yes, based on the licensing requirements suggested by the Commission basic scientific research involving embryos would be permissible subject to limitations. The two pertinent recommendations state that:

(g) [a]ll research on human zygotes must be undertaken only for purposes of promoting understanding and treatment of human health . . .

(h) [t]he objective of research on human zygotes should be achievable only through human zygotes.

(Proceed With Care Rec. 198 (g) (h) p. 648.)

- B. **ARE ANY TYPES OF PROCEDURES PROHIBITED?** The Commission recommends that research concerning "ectogenesis, cloning, animal/human hybrids, and the transfer of zygotes to another species" be prohibited. (Rec. 184 at p. 637) Ectogenesis "refers to the idea of supporting the development of a zygote into an embryo and fetus outside a uterus until it is 'born' or able to exist independently" (Proceed With Care p.743). Additionally, research involving genetic alteration of embryos would not be permissible pursuant to the

Commission's recommendations. (Rec. 185 at p.638)

### III. DOES THE LEGISLATION DEFINE:

A. **"EMBRYO"?** The Commission notes a problem with terminology in that the term "embryo" is used in different ways. (Proceed With Care n. p.607) They acknowledge that biologists define embryo as "the developing entity after implantation in the uterus until about eight weeks after fertilization" (*id.*) and "zygote" is the appropriate term to describe a fertilized egg before implantation. (*id.*) However, the term embryo is commonly used in the public debate so the Commission will continue to utilize it, but will also "refer to the developing entity during the first 14 days as a zygote." (*id.*)

B. **"EXPERIMENTATION" AND/OR "RESEARCH"?** In Recommendation 195, the Commission asserts that "experimental" and "innovative" therapies should fall under the rubric of research (*id.* at 646).

IV. **IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION?** The Commission recommends the "[a]ll research using human zygotes be subject to compulsory licensing by the National Reproductive Technologies

Commission." (Rec. 193 at p. 645)

**A. COMPOSITION:** It is recommended that the Commission be composed of 12 members appointed by the Governor in Council (Proceed With Care p. 1023). The Commission suggests that "a substantial proportion" of the members should be women (id.). The committee members should include individuals with a knowledge of, and interest in "those with disabilities, those who are infertile, and those who are members of a racial minority, Aboriginal, and economically disadvantaged communities" (id.). Additionally, expertise in various areas including medicine, ethics, law and social science should be reflected in the Commission's composition (id.). It was also recommended that to best address the many facets of reproductive technology, six subcommittees should be formed. The subcommittees "would focus on infertility prevention; assisted conception; assisted insemination; prenatal diagnosis and genetics; human zygote/embryo research; and the provision of fetal tissue for use in research" (id.). Specific suggestions with regard to the composition of the subcommittees are also made. These recommendations are similar to those concerning composition of the National Commission (id. at 1023-4). In addition, it is recommended that the membership should include

Commission and non-Commission members who have a particular interest in the area of focus of the subcommittee (id.).

**B. AUTHORITY/RESPONSIBILITY:** The Report recommends generally that the Commission be "charged with the primary responsibility of ensuring that new reproductive technologies are developed and applied in the national public interest" (Proceed With Care, Rec. 1 at 112). The Royal Commission proposes several functions to be performed by the National Commission including: "licensing and monitoring; guideline and standard setting; information collection, evaluation and dissemination; records storage; consultation, coordination, and intergovernmental cooperation; and monitoring future technologies and practices" (Proceed With Care p. 116). The Royal Commission suggests what the responsibility of each subcommittee should entail, including those of the Embryo Research Subcommittee. This subcommittee will be responsible for "developing standards and guidelines to be adopted as conditions of license and for overseeing the implementation of the National Commission's licensing program" (id. Rec. 197 at 647).

**C. GRIEVANCE PROCEDURE:** No specific grievance procedure



is outlined, however, "[t]he National Commission's decision to approve or deny a license would be subject to appeal to the Federal Court of Canada on matters of jurisdiction" (Proceed With Care p. 117).

## **V. QUALITY ASSURANCE MECHANISMS**

- A. AUTHORIZED SITE?** If a zygote is created for research purposes, the Commissioners assert that "the research must be done in a facility licensed for such research." (Proceed With Care, p. 638.) In addition, the Commission proposes that facilities be required to meet National Reproductive Technology Commission (NRTC) requirements to receive a license. (See Proceed With Care at 645.) "Facilities that applied and met the NRTC's licensing conditions would receive a license to conduct research using human zygotes for a period of five years." (Id.)
- B. AUTHORIZED PRACTITIONER?** Yes, the Commission recommends that "[l]icensing requirements for zygote/embryo research apply to any physician . . . using human zygotes in research." (Proceed With Care Rec. 195 p. 646.) The licensing requirement will be determined by the Embryo Research Sub-Committee. (See Proceed With Care, p. 1029.)

C. **RECORDKEEPING?** Yes, Recommendation 198(e) requires the following as a condition for a license:

(e) Proper documentation showing the source of gametes, and signed donor consent forms, must accompany all gametes used to create zygotes for research. This documentation must be retained in the documentation relating to the research project and kept in a secure manner . . .

(Proceed With Care Rec. 198(e) p. 648). In addition, individuals engaging in embryo research must file an annual report and summary of its activities with the National Reproductive Technologies Commission (Proceed With Care Rec.198(k) p. 649).

## VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR

A. **INFORMED CONSENT?** Yes, researchers will only be permitted to use zygotes for research where the persons donating the gametes used in the creation of the zygote have given fully informed consent to the use of the embryos in research (Rec. 186 at p.639). The Commission issued this recommendation as a measure to ensure an individual's autonomy in controlling his or her body (Proceed With Care at 639). They were concerned that couples in in vitro fertilization programs would feel pressured to donate zygotes or

gametes for research (id.). Informing donors of risks and benefits resulting from potential uses of their gametes was also found to be necessary for decisions regarding disposition and storage of donors' zygotes (id.).

B. **COUNSELLING?** Although counselling is not specifically mentioned in the research context, the Commission recommends that it "should be an integral part of assisted conception services . . . ." (Proceed With Care, Rec. 151, p. 571.)

C. **MARITAL STATUS?** Although the issue of marital status is not expressly mentioned with regard to research, concerning in vitro fertilization, the Commission recommends that, "[a]ccess to IVF treatment should be determined . . . without discrimination on the basis of factors such as marital status." (Proceed With Care, Rec. 145, p. 569.)

## VII. PENALTIES

Specific penalties are not recommended by the Committee, but they do recommend criminalization of "zygote/embryo research related to ectogenesis, cloning, animal/human hybrids, the transfer of zygotes to another species . . . ." (Proceed With Care, p. 1022, See Rec. 184, p. 637.)

**COUNTRY: DENMARK**

- I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP? A committee operating under the Danish Government issued a report entitled "Ethical Problems with Egg Transplantation, Artificial Insemination by Donor and Research on Embryos" in 1984 (OTA, Infertility: Medical and Social Choices, "Appendix E: International Developments" p. 347 (May, 1988)). The report concluded that legislation was not necessary at that point but a standing review and advisory committee should be established (id.). In 1987, by legislative enactment, the Minister of the Interior was charged with setting up an Ethical Council that would have the responsibility of making recommendations for legislation and reporting on the state of research in the fields of genetic treatment, diagnostic techniques for detecting congenital anomalies and cryopreservation (See, Law No. 353 of June 1987 secs. 1, 5, 6, and 7). The Council has 18 members, eight appointed by the Minister of the Interior and ten by Parliament (Morgan, D. and Nielsen, L., "Prisoners of Progress or Hostages to Fortune?" at 21(1) Journal of Law, Medicine and Ethics 30-42 at 32, Spring, 1993).
- II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes, Order No. 650 of 22 July 1992 on the freezing and donation

of human oocytes and Law No. 503 of 24 June 1992 on the scientific ethics committee system and the examination of biomedical research projects which amends Law No. 353 of 3 June 1987. Law No. 503 allows embryo research if it is approved by both a regional and central review committee. The purpose of the research must be to improve in vitro fertilization so as to bring about pregnancy. The reason for allowing such research "is that IVF is a recognized treatment and that research is accepted internationally as an integrated part of the development of treatment; prohibiting all research would mean consciously offering less optimal treatment than possible" (Morgan, D. and Nielsen, L. p.32).

The law requires that fertilized oocytes not be kept alive outside the uterus beyond 14 days from the point of fertilization excluding a period of storage (Order No. 650 sec.5 and Law No. 503 sec. 14(5)).

**A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** No, the Act forbids "experiments whose purpose is to enable the production of genetically identical human beings" (sec. 15 (1)).
2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?** This

procedure is seemingly acceptable by implication. Section 14(4) provides that fertilized oocytes that have been used in research cannot be implanted unless there is no risk of transmitting hereditary diseases, defects, abnormalities or deformities. This provision would seem to allow, if not require, preimplantation diagnosis (see, Morgan, D. and Nielsen, L. p.p.32-33).

3. **IVF EXPERIMENTAL TECHNIQUES?** Yes, the statute provides that: "[b]iomedical research on fertilized human oocytes . . . may . . . only be carried out . . . if the purpose of such research is to improve *in vitro* fertilization in order to bring about pregnancy" (sec.14(1)).
4. **GENE THERAPY FOR EMBRYOS?** This technique will likely not be permitted as it generally is not utilized as a means to improve *in vitro* fertilization as is required by Section 14(1).
5. **CRYOPRESERVATION?** Cryopreservation is likely to be permitted considering that the legislation provides that "[t]he Minister of Health shall be empowered to issue regulations on the freezing . . . of human oocytes" (sec.14(4)).

6. **BASIC SCIENTIFIC RESEARCH?** No. The Act specifies that "[b]iomedical research on fertilized human oocytes . . . may . . . only be carried out if the purpose of such research is to improve *in vitro* fertilization in order to bring about pregnancy." (sec.14(1)). This requirement would foreclose the possibility of using fertilized oocytes for the purpose of advancing general scientific knowledge.

**B. ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?**

Specific prohibitions of types of experimentation are also articulated. Sec. 15 of Law No. 503 prohibits experiments to produce genetically identical human beings (Law No. 503 sec.15(1)); experiments to create chimeras (Law No.503 sec.15(2)); experiments to produce hybrids (Law No.503 sec.15(3)); and experiments to develop humans in the uterus of another species (Law No.503 sec.15(4)).

**III. DOES THE LEGISLATION DEFINE:**

**A. "EMBRYO"?** No mention.

**B. "EXPERIMENTATION" AND/OR "RESEARCH"?** No mention.

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION?** Yes, regional committees and the Central Scientific Ethics Committee (Law No. 503 sec.14). The Central Scientific Ethics Committee is established by the Minister of Education and Research (International Digest of Health Legislation, 1992,43(4):758, citing Law No. 503 sec. 4).

**A. COMPOSITION:** There are seven regional committees which are formed in accord with local government boundaries. (Morgan, D. and Nielsen, L., "Prisoners of Progress or Hostages to Fortune?" in the *Journal of Law, Medicine, and Ethics* 21(1):30-42 (Spring, 1993)). Each committee has either nine or 11 members, three of whom are nominated by the state authorized scientific committee (id.). The Central Scientific Ethics Committee consists of two members appointed by the Minister of Education and Research; two by each regional committee; and two by the Minister of Health (id.).

**B. AUTHORITY/RESPONSIBILITY:** The committees are to make scientific assessment of projects (see, International Digest of Health Legislation 1992, 43(4):759, citing Law No. 503 sec.7). The committees are responsible for evaluating the risks of projects, ensuring that subjects are adequately informed and give voluntary



consent and that the projects conform to scientific standards and that sufficient grounds exist for carrying them out (id. citing sec.8). The committees must also keep informed of developments in biomedical research and disseminate the ethical issues these developments raise (id. citing sec.10). The Central Committee is responsible for coordinating the work of the committees; setting out guidelines and advising the regional committees on issues of science and ethics; monitoring developments and examining submitted research projects (id. citing sec.11).

C. GRIEVANCE PROCEDURE: No mention.

#### V. QUALITY ASSURANCE MECHANISMS

A. AUTHORIZED SITE? No mention.

B. AUTHORIZED PRACTITIONER? No mention.

C. RECORDKEEPING? No mention.

#### VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR

A. INFORMED CONSENT? It is implied that informed consent is a requirement in that the committees are charged

with ensuring that patients or research subjects are fully informed orally and in writing about the risks and benefits of the project and the content of the project (sec. 8).

**B. COUNSELLING?** No mention

**C. MARITAL STATUS?** No mention.

## **VII. PENALTIES**

Yes.

COUNTRY: FRANCE

I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP? In 1983, the French National Consultative Ethics Committee on Life and Medical Sciences (Comite Consultatif National d'Ethique Pour les Sciences de la Vie et de la Sante; CCNE) was created by the President (OTA, Biomedical Ethics in U.S. Public Policy, Appendix A: International Bioethics Initiatives p.46 (1993)). CCNE set up several groups to report on issues related to new reproductive technologies. In 1986, CCNE published a report on the ethics of research on human embryos (Infertility: Medical and Social Choices, p. 339). That same year, the Prime Minister requested that Conseil d'Etat complete a legal study to expand on the work done by CCNE (Law Reform and Human Reproduction, p. 142). The Conseil issued recommendations which were considered by a governmental working group which subsequently presented a Bill to Parliament opposed to the creation of embryos for research (see, Hornett, S. "Embryos and Europe: What Prospects for Harmonisation?" in *New Law Journal*: 713 (May 24, 1991)). In 1992, the Special Commission on Bioethics of the French National Assembly presented recommendations which formed the basis of draft legislation (*Financial Times Limited, Biotechnology Business News*, July 17, 1992). In these

"analysis of molecular and chromosomal genetics in view of establishing a prenatal diagnostic" may be performed by authorized health establishments.

(Art. L. 673-6).

3. **IVF Experimental Techniques?** Yes, the legislation would appear to permit IVF experimental procedures since procedures can be undertaken on the embryo to facilitate procreation. (Art. L. 671-2).

4. **Gene Therapy for Embryos?** Yes, presumably, since the Code specifically allows prenatal diagnosis for "therapeutic intervention on the embryo . . . . to treat an ailment of a particular gravity." (Art. L. 673-6).

5. **Cyropreservation?** Yes, the Code states that "at the request of both partners of the couple, the embryos that were not transferred can be conserved in view of the future pursuit of their parental project." (Art. L. 671-2). The Code further allows for the conservation to last for five years unless the couple wishes to pursue the project past that time. (Id.)

6. **Basic Scientific Research?** Yes, when the couple

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6. **Basic Scientific Research?** Yes, when the couple

no longer wish to preserve their embryos, they can consent to the use of the embryos in scientific research. (Art. L. 671-2 bis).

The Code further states that:

Research projects on the human embryo are submitted to prior opinion of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics, in accordance with the methods defined by a decree in the Conseil d'Etat. Each year this commission renders a public list of establishments performing research on the embryo together with the purpose of the research. (Art. L. 672-7).

**B. ARE ANY TYPES OF EXPLICITLY PROCEDURES PROHIBITED?**

Yes, commercial and industrial uses of embryos are prohibited. (Art. L. 671-2 ter).

**III. DOES THE LEGISLATION DEFINE:**

**A. "EMBRYO"?** No mention.

**B. "EXPERIMENTATION" AND/OR "RESEARCH"?** No mention.

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION?** Yes, the National Consultative Commission on the Ethics for Life Sciences and Medicine. (Art. IA).

**A. COMPOSITION:** The Commission is composed of a president who is nominated by decree of the President of the Republic (Art. IA). Other Commission members include individuals chosen by the President of the Republic and members of the principle philosophical and spiritual families (id.); individuals qualified because of competence and interest in the problems of ethics (id.); one member of the National Assembly and one member of the Senate appointed by the president of each of these bodies (id.). In addition, persons in the research community should be members (id.).

**B. AUTHORITY/RESPONSIBILITY:** The Commission gives advice on the ethical problems that are raised by research and practice in the fields of biology, medicine and health (Art. IA). The Commission informs the public about questions relevant to these subjects, and participates in the development of instruction concerning biomedical ethics (id.). The Commission submits to the President and to Parliament an annual report regarding the results of its activities (id.).

**C. GRIEVANCE PROCEDURE:** No mention.

**V. QUALITY ASSURANCE MECHANISMS**

- A. AUTHORIZED SITE?** The Code limits the occurrence of any research or diagnostic activities to health establishments of laboratories authorized by the Commission (Art. L. 673-6). In addition, "[c]linical and biological acts of medically assisted procreation, . . . are performed . . . in each establishment or in laboratory authorized to practice them" (Art. L. 671-3).
- B. AUTHORIZED PRACTITIONER?** Under the Act, "[c]linical and biological acts of medically assisted procreation, defined by decree in the Conseil d'Etat, are performed under the responsibility of a practitioner specifically approved for such purpose in each establishment or laboratory authorized to practice them" (Art. L. 671-3).
- C. RECORDKEEPING?** There is a recordkeeping requirement with respect to prenatal diagnosis. The Code provides for the establishment of Registers to be kept by authorized health establishments. The Registers will indicate and verify the causes for the therapeutic pregnancy interruption (Art. L. 673-6).

## **VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR**



- A. INFORMED CONSENT?** After a month of reflection regarding counselling by the physician (outlined below), the parties must authorize in writing their request for in vitro fertilization (Art. L. 671-3 bis). With respect to research on the embryo, both parties must provide consent. (Art. L. 671-2 bis).
- B. COUNSELLING?** During a private interview with both partners, the authorized physician must: verify the motivation of both partners and recall the possibilities of adoption; inform the parties of the possibilities of success and failure as well as the possible pain of in vitro fertilization. (Art. L. 671-3 bis). Finally, the authorized physician must provide the parties with the legislative and regulatory provisions regarding in vitro fertilization, a description of the techniques, and recall the legislative provisions regarding adoption (id.).
- C. MARITAL STATUS?** The Code states that: "No embryo can be conceived in vitro outside of the parental project" (Art. L. 671-2 bis). The Code does not explicitly define "parental project"; however, the Code does state that: "The man and woman forming the couple, at an age of procreating, must be alive and consensual at the time of . . . implantation of the embryos" (Art. L.

671-2).

## VII. PENALTIES

The Code provides a detailed list of penalties for violation of the previously outlined provisions in Chapter II of Title III of Book IV of the Public Health Code titled "Sanctions Relative to Medically Assisted Procreation and Prenatal Diagnostics."

The Code allows for revocation of a health establishment's authorization to perform in vitro fertilization of prenatal diagnostics (Art. L. 682-1); and, for imprisonment and fine where a person performs in vitro fertilization without the proper authorization (Art. L. 682-8).

The acts of collecting or attempting to collect embryos without written consent (Art. L. 682-2); of obtaining or attempting to obtain gametes or embryos for a payment (Art. L. 682-3); of divulging the identities of donors or donees of gametes or embryos (Art. L. 682-4); and of collecting gametes or embryos without proceeding with tests to detect transmissible or genetic diseases of the donors (Art. L. 682-5), are punished by imprisonment and fine.

COUNTRY: GERMANY

I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP? The Federal Ministry for Research and Technology collaborated with the Ministry of Justice to recommend limitations on noncoital reproduction. This joint effort resulted in the Benda Report which served as a basis for the Embryo Protection Law 1990 (Law Reform and Human Reproduction p. 35).

II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes, The Embryo Protection Law 1990. This law criminalizes creating embryos for any reason other than in vitro fertilization to bring about pregnancy of the woman from whom the embryo derived. Additionally, all research using, destroying or wasting embryos is prohibited (sec. 2(1)).

No limitations are expressed because the Act does not speak to permissible research on embryos.

A. DOES THE LEGISLATION PERMIT:

1. TWINNING? No, "[a]ny person who artificially causes a human embryo to develop with the same genetic information as another embryo . . . shall

be punished by up to five years' imprisonment or by a fine" (sec. 6(1)).

2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?** No, because a potential outcome of genetic screening is destruction of or failure to transfer certain embryos, the legislation is likely to forbid this technique. The Act provides that any person who uses an embryo "for a purpose other than its preservation, shall be punished by up to three years' imprisonment or by a fine" (sec. 2(1)).
3. **IVF EXPERIMENTAL TECHNIQUES?** Yes, if done for the purpose of achieving pregnancy, and such research does not potentially destroy the embryo.
4. **GENE THERAPY FOR EMBRYOS?** No, the Act expressly prohibits alteration of the genetic information of the human germline cell (sec.5(1)). Exceptions to punishment apply if the germline cell is outside the body and there is no chance that the cell will be used in fertilization (sec. 5(4)(1)) and if the cell modified is from a dead conceptus (sec.5(4)(2)).
5. **CRYOPRESERVATION?** The act does not mention this

procedure, but it does penalize "attempts to fertilize more egg cells from a woman than may be transferred to her within one treatment cycle (Sec.1(5)). This would imply that no spare embryos are created to necessitate the use of cryopreservation techniques.

6. **BASIC SCIENTIFIC RESEARCH?** No, the law prohibits using embryos for research (see sec. 1(2)).

**B. ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?** The statute criminalizes:

- 1) creation of embryos for purposes other than pregnancy of the woman from whom the ova originated (sec. 1(1)(2))
- 2) sex selection other than to prevent a sex-linked hereditary disease (sec. 3)
- 3) artificial alteration of germline cells (sec. 5)
- 4) cloning (sec. 6)
- 5) creation of chimeras and hybrids (sec. 7)

**III. DOES THE LEGISLATION DEFINE:**

A. "EMBRYO"? Yes, "embryo":

"means the human egg cell, fertilized and capable of development, from the time of fusion of the nuclei, as well as each totipotent cell removed from an embryo that is capable, in the presence of other necessary conditions of dividing and developing into an individual." (sec. 8(1))

B. "EXPERIMENTATION" AND/OR "RESEARCH"? No mention.

IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION? No mention.

A. COMPOSITION: No mention.

B. AUTHORITY/RESPONSIBILITY: No mention.

C. GRIEVANCE PROCEDURE: No mention.

V. QUALITY ASSURANCE MECHANISMS

A. AUTHORIZED SITE? N/A

B. AUTHORIZED PRACTITIONER? The law provides that only a physician may perform "artificial fertilization . . . and the preservation of a human embryo or a human egg cell which has already been penetrated by, or has had artificially introduced into it, a human sperm cell"

(sec. 9).

C. RECORDKEEPING? N/A

## VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR

A. INFORMED CONSENT? Although the Act does not speak to research, it does penalize "any person who: attempts to artificially fertilize an egg cell without the woman whose egg cell is to be fertilized and the man whose sperm cell is to be used for fertilization, having given consent" (Sec. 4(1)(1)).

B. COUNSELLING? N/A

C. MARITAL STATUS? N/A

## VII. PENALTIES

A penalty of up to one year imprisonment or a fine will be imposed on one performing sex selection for reasons other than preventing a sex-linked disorder. (sec. 3) A penalty of up to 3 years imprisonment or a fine is imposed for creating embryos for purposes other than implantation (sec. 1(1)(2)), and creation of spare embryos (sec.1(1)(5)). A penalty of up to 5 years imprisonment or a fine is imposed on an individual who artificially alters germline cells or

attempts to do so (sec. 5), engages in cloning embryos or attempts to do so (sec. 6) or creates or attempts to create chimeras or hybrids.



COUNTRY: NORWAY

I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP? The precursors to Norway's law Relating to Procreation were ethical guidelines for Artificial Insemination and *In Vitro* Fertilization by the Council on Medical Ethics in 1983 and a legislative proposal drafted by a group of ministers in 1986. The Council had recommended that research on embryos be reviewed by medical ethics committees. (Infertility: Medical and Social Choices, p. 352)

II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes, Law No. 68 of 12 June 1987 on artificial fertilization. The Law imposes criminal sanctions for performing any research on fertilized eggs.

Since no research is permissible, no limitations are articulated.

A. DOES THE LEGISLATION PERMIT:

1. **TWINNING?** No, the Act prohibits research on fertilized eggs (sec.3).

2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?** No, the Act prohibits research on fertilized eggs (sec. 3). The Act only allows for fertilization outside the body if a woman is sterile (sec.12). The Act does not contemplate using in vitro fertilization techniques to prevent transmission of a serious disease, therefore it would seem that preimplantation genetic screening would not be permitted.
3. **IVF EXPERIMENTAL TECHNIQUES?** No, the Act prohibits research on fertilized eggs (sec.3).
4. **GENE THERAPY FOR EMBRYOS?** No, the Act prohibits research on fertilized eggs (sec. 3).
5. **CRYOPRESERVATION?** Although the freezing of unfertilized eggs is prohibited, authorized institutions may freeze fertilized eggs (sec.3). Frozen fertilized eggs "may be utilized only for implantation in women and may not be preserved for more than 12 months" (sec.3).
6. **BASIC SCIENTIFIC RESEARCH?** No, the Act prohibits research on fertilized eggs (sec. 3).

**B. ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?**

Sec. 3 prohibits research on fertilized eggs.

Additionally, sec. 3 specifies that frozen fertilized eggs cannot be used for any purpose other than implantation.

**III. DOES THE LEGISLATION DEFINE:**

**A. "EMBRYO"?** No mention.

**B. "EXPERIMENTATION" AND/OR "RESEARCH"?** No mention.

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF**

**THE LEGISLATION?** All institutions performing artificial fertilization must be approved by the Ministry of Social Affairs and submit a report of its activities to the Ministry. (sec. 2) Because the legislation prohibits research, though, it is not clear whether the Ministry also acts to enforce the prohibition on research.

**A. COMPOSITION:** No mention.

**B. AUTHORITY/RESPONSIBILITY:** No mention.

**C. GRIEVANCE PROCEDURE:** No mention.

**V. QUALITY ASSURANCE MECHANISMS**

**A. AUTHORIZED SITE? N/A**

**B. AUTHORIZED PRACTITIONER? N/A**

**C. RECORDKEEPING? N/A**

**VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR**

**A. INFORMED CONSENT? N/A**

**B. COUNSELLING? N/A**

**C. MARITAL STATUS? N/A**

**VII. PENALTIES**

Sec. 14 provides that intentionally carrying out research in contravention of this law is subject to fine or imprisonment not to exceed 3 months. Accomplices are liable to the same penalties. Additionally, if the offense is committed on behalf of a company, association or institution or public agency, that entity shall be liable to a fine.

COUNTRY: SPAIN

I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT OR OTHER INTEREST GROUP? The parliamentary commission for the study of Human In Vitro Fertilization and Artificial Insemination proposed legislative and regulatory action in this field (Infertility: Medical and Social Choices, p. 353 ). Their recommendations included approval of limited embryo experimentation (id.).

II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes, two pieces of legislation address the issue of embryo research: Law No. 35/1988 on assisted reproductive procedures and Law No. 42/1988 on donation of human embryos and fetuses or their cells, tissues, or organs. The legislation addresses many issues raised by new reproductive technologies. The Laws address in vitro fertilization, artificial insemination, gamete intra-fallopian transfer, donation of gametes and embryos and embryo experimentation. The laws are very detailed with regard to the techniques which are permissible and under what conditions.

Experimentation on live pre-embryos obtained in vitro is not permitted until it is proven that animal models are inadequate (Law No. 35/1988 sec. 16 (2)); pre-embryos in

utero or in the fallopian tubes cannot be experimented on (Law No. 35/1988 sec. 16 (4)) and non-therapeutic research is only permitted on non-viable, surplus embryos (Law No.35/1988 sec. 15). In addition, research must be performed within 14 days of fertilization (Law No.35/1988 sec.15 (1)(b)).

**A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** No, under the law it is considered a "very serious offense" to "creat[e] human beings by cloning in any of its variants, or any other procedure capable of yielding several identical human beings" (Law No. 35/1988 sec. 20(2)(1)).

2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?**

Yes, section 12(1) provides that an intervention on a pre-embryo for diagnostic purposes "may have as its sole objective the enhancement of its viability or the detection of hereditary diseases with a view to their treatment if this is possible, or with a view to advising against their transfer for purposes of procreation" (Law No. 35/1988 12(1)). Research on pre-embryos *in vitro* is permissible for diagnostic purposes (Law No. 35/1988 sec.15(2)(a)). The Act may even be read

to require this technique; it is considered to be a "very serious offense" to "transfer[] to the uterus gametes or pre-embryos without the necessary biological or viability assurances" (Law No. 35/1988 sec.20(2)(i)). What those "assurances" are is not defined, but this clause does seem to imply that preimplantation screening is not only permissible but required.

3. **IVF EXPERIMENTAL TECHNIQUES?** Yes, under the section of the legislation entitled "Research and Experimentation", the statute provides that "the improvement of procedures for assisted reproduction and associated manipulations . . . and techniques for acquiring better knowledge of the criteria of viability for pre-embryos obtained *in vitro* and the optimum timing for their transfer to the uterus" shall be authorized subject to various conditions (Law No. 35/1988 sec.16(1)(a)).
4. **GENE THERAPY FOR EMBRYOS?** Yes, if "there is no influence on non-pathological hereditary traits, and no selection of individuals or race is sought" (Law No. 35/1988 sec.13(3)(d)). The Law provides that "[a]ny intervention upon the live pre-embryo *in vitro* for therapeutic purposes [that] may have

as its sole objective the treatment or prevention of the spread of a disease, where there are reasonable and verified prospects of success" (Law No.35/1988 sec. 13(1)).

5. **CRYOPRESERVATION?** Yes, the Law provides that the improvement of procedures for cryopreservation shall be authorized (sec.16(1)(a)).

6. **BASIC SCIENTIFIC RESEARCH?** Yes, the Law provides that "basic research on the origin of human life in its initial phases, cellular aging, and cell division, meiosis, mitosis and cytokinesis" shall be authorized (Law No. 35/1988 16(1)(b)).

**B. ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?**

Twenty-four actions involving embryos or pre-embryos are considered to be "very serious offenses" under Law No. 35/1988 sec.20 (2)(B)(a)-(x). Included as "very serious offenses" are: fertilization for purposes other than procreation (Law No. 35/1988 sec.20(2)(B)(a); maintaining in vitro embryos beyond 14 days from fertilization, excluding time subject to cryopreservation (Law No. 35/1988 sec. 20 (2)(B)(c)); commercialization of pre-embryos or their cells (Law



No. 35/1988 sec. 20(2)(B)(e)); creating human beings by cloning or other procedures directed to selection of traits (Law No. 35/1988 sec.20(2)(B)(k)); cloning to create identical persons (Law No. 35/1988 sec.20(2)(B)(l)); sex selection for non-therapeutic purposes (Law No. 35/1988 sec.20(2)(B)(n)); creating chimeras (Law No. 35/1988 sec.20(2)(B)(p)) or hybrids (Law No. 35/1988 sec.20(2)(B)(q)); transferring human pre-embryos to the uterus of another species or the reverse (Law No. 35/1988 sec.20(2)(B)(r)); and biological warfare techniques (Law No. 35/1988 sec.20(2)(B)(v)).

**III. DOES THE LEGISLATION DEFINE:**

**A. "EMBRYO"?** No mention.

**B. "EXPERIMENTATION" AND/OR "RESEARCH"?** No mention.

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION?** Yes, the National Commission on Assisted Reproduction (Law No. 35/1988 sec.21) and the National Commission for Supervision and Control of the donation of human embryos and fetuses (Law No. 42/1988). Both commissions, at the time of the legislative enactment were in the process of being formed pursuant to legislative

mandate (Law No. 35/1988 sec. 21 and Law No. 42/1988, Additional Provisions sec. 1(f)).

**A. COMPOSITION:** The National Commission on Assisted Reproduction, when it is created, is to be comprised of representatives of Government and the Administration, representatives from associations with an interest in human fertility and a Council with a diverse social composition (Law No. 35/1988 sec. 21(3)). Law No. 42/1988 has left to be determined the requirements for establishing the National Commission for Supervision and Control (Law No. 42/1988 Chapter IV 1 (f)).

**B. AUTHORITY/RESPONSIBILITY:** The authority of the National Commission on Assisted Reproduction will include providing guidance on the use of reproductive technologies, compiling and updating scientific and technical knowledge in cooperation with the Administration and developing criteria for centers delivering assisted reproductive services (Law No. 35/1988 sec.21(1)). Once the particular functions of the Committee are determined by Government, the commission is to set up its own rules and regulations subject to Government approval (Law No. 35/1988 sec.21(4)). The authority of the National Commission was to be determined by the Government within six

months of the promulgation of Law No. 42/1988 (Law No. 42/1988 Chapter IV sec.1(f)).

C. **GRIEVANCE PROCEDURE:** No mention.

V. **QUALITY ASSURANCE MECHANISMS**

A. **AUTHORIZED SITE?** Yes (Law No. 35/1988 sec.15(1)(c) and Law No. 42/1988 sec.3(1)). Law No. 35/1988 mandates that research on live pre-embryos can only be authorized if "the research is carried out in medical centres" (sec. 15 (1)(c)). Sec. 18 states that

[a]ll centres or services in which the procedures for assisted reproduction, or subsidiary procedures, are performed . . . shall be considered public or private health centres or services, and shall be governed by the provisions of the General Law on Health [No. 14/1986 of 25 April 1986] and the regulations made for its implantation or in accordance with the [decisions of] the public administrations responsible for health matters.

(International Digest of Health Legislation, 1989,40(1):

89, quoting Law No. 35/1988 sec.18). Law No. 42/1988 provides that using human embryos or their biological structures can only be done "at centres or services that are authorized and supervised by the public authorities" (Law No. 42/1988 sec. 3(1)).

**B. AUTHORIZED PRACTITIONER?** Yes (Law No. 35/1988 sec. 15 (1)(c) and Law No. 42/1988 sec. 3(1)). Law No. 35/1988 requires that research on live pre-embryos be carried out "by approved, qualified, and authorized multidisciplinary scientific teams, under the control of the competent public authorities" (sec. 15 (1)(c)). Chapter V of the Law, "Health Centres and biomedical teams" provides that biomedical teams working in the health centers (described supra) must be:

specially qualified to perform procedures for assisted reproduction, their associated applications, or related scientific activities, and shall for this purpose have the necessary equipment and resources. They shall work in an interdisciplinary manner, and the director of the centre or service to which they are subordinate shall be directly responsible for their activities.

(Law No. 35/1988 sec.19(1)). Law No. 42/1988 requires that use of human embryos or their biological structures only be by "fully qualified biomedical teams" (sec.3(1)). The Law does not describe what constitutes "fully qualified." One restriction on the medical team, though, is that the team that performs the termination of a pregnancy "may not be involved in the utilization of the embryo or fetus or their biological structure under the conditions and for the purposes provided for in this law" (sec.3(3)).

**C. RECORDKEEPING?** Yes, Law No. 35/1988 requires documentation of any experimental project on non-viable pre-embryos in vitro (Law No. 35/1988 sec.16 (3)); under Law No.42/1988 the teams engaged in research or experimentation must convey the results to the authority approving the protocol directly or through the National Commission for Supervision and Control (Law No. 42/1988 sec.7(2)).

## **VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR**

**A. INFORMED CONSENT?** Yes (Law No.35/1988 sec.15(1)(a) and Law No.42/1988 sec.2(b)). Under Law No. 35/1988, one requirement that must be met for research on pre-embryos to be authorized is that the individuals from whom the pre-embryos originate must give their written consent "after a prior detailed explanation of the objectives of the research and its implications" (sec. 15(1)(a)). Under Law No. 42/1988, donated embryos may be utilized for research or any other purpose prescribed in the Law if "the donors have given their prior written consent, such consent being free, express and informed" (sec. 2(b)).

**B. COUNSELLING?** No mention.

C. **MARITAL STATUS?** Since embryos used for research or experimentation would only be available as a result of assisted reproductive procedures, it is necessary to consider the section of the law which addresses the issue with regard to persons undergoing these procedures. The language used in the pertinent section in Law No. 35/1988 suggests that marriage is not a requirement. Law No. 35/1988 sec.6(2) refers to "a woman who wishes to undergo" assisted reproduction procedures as needing to be informed of potential risks. The following section states that "[i]f the woman is married, a spouse's consent shall likewise be required . . ."(Law No. 35/1988 sec.6(3)). By implication, this indicates that marriage is not a requirement for participation in assisted reproduction programs and thereby in programs with regard to embryo research or experimentation. Law No. 42/1988 makes no mention of marital status.

## VII. PENALTIES

Law No. 35/1988 Sec. 20 makes it a "serious offense" not to comply with regulatory requirements and omit data, consents and references required by the regulations.

Further, sec. 20 states a number of different violations that constitute "very serious offenses." The regulations

make no mention of what penalties are imposed for "serious" and "very serious" offenses.

**COUNTRY: SWEDEN**

**I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP?** Prior to the enactment of legislation, the Swedish Government had appointed the Committee on Genetic Integrity to study various issues related to genetic engineering (Infertility: Medical and Social Choices p., 343).

**II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH?** Yes, Law No. 115 of 14 March 1991 concerning measures for the purposes of research or treatment in connection with fertilized human oocytes. The statute is very general, not specifying what types of research are permissible. Several limitations are imposed which will be discussed at II. B.

Research must be performed within 14 days from the time of fertilization (Law No. 115 sec.2). At the end of 14 days, any embryo experimented upon must be destroyed (id.).

Additionally, fertilized oocytes utilized for experimental purposes cannot be transferred to a woman (Law No. 115 sec.4).

**A. DOES THE LEGISLATION PERMIT:**



1. **TWINNING?** The law does not prohibit twinning and as a result of the statute's general language this may be permissible. However, the embryo experimented on may not be introduced into a woman's body (Law No.115 sec.4).
2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYO?**  
Although research may be permissible on this technique "[f]ertilized oocytes that have been used in an experiment for the purposes of research or treatment may not be introduced into the body of woman" (Law No.115 sec.4).
3. **IVF EXPERIMENTAL TECHNIQUES?** Because the technique of in vitro fertilization is performed in Sweden (see Law No.711) and experimentation on embryos is permissible, it is likely that in vitro fertilization experimental techniques are permitted.
4. **GENE THERAPY FOR EMBRYOS?** This procedure is likely to be permitted as long as the purpose of the experimentation is not "to develop methods aimed at causing heritable genetic effects" (Law No. 115 sec.2). Section 2 provides that "[a]ny experimentation on fertilized oocytes for the

purposes of research or treatment shall be carried out within a maximum period of 14 days from the time of fertilization . . . At the end of the period referred to . . . any fertilized oocyte that has been used in experimentation shall be immediately destroyed" (Law No.115 sec.2).

5. **CRYOPRESERVATION?** Yes, fertilized oocytes may be cryopreserved for a maximum of one year unless a longer time is specified by the National Board of Health and Welfare (Law No. 115 sec.3).

6. **BASIC SCIENTIFIC RESEARCH?** Yes, since embryo research is permitted and no explicit purposes are defined for such research, nor is such research explicitly prohibited, the legislation would seem to allow embryos to be utilized for basic scientific research so long as they will not be implanted.

B. **ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?** The Law prohibits experimentation "to develop methods aimed at causing heritable genetic effects" (Law No. 115 sec. 2).

**III. DOES THE LEGISLATION DEFINE:**

**A. "EMBRYO"?** No mention.

**B. "EXPERIMENTATION" AND/OR "RESEARCH"?** No mention.

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION?** This is unclear, but the National Board of Health and Welfare does have authority over the storage of fertilized oocytes (Law No. 115 sec. 3, 5, and 7) and has issued recommendations on extra corporeal fertilization.

**A. COMPOSITION:** No mention.

**B. AUTHORITY/RESPONSIBILITY:** The National Board of Health and Welfare does have authority to extend the period of time for which fertilized oocytes may be stored (secs. 3 and 5).

**C. GRIEVANCE PROCEDURE:** The Law is not specific with regard to research or experimentation, but it does provide that decisions by the National Board of Health and Welfare concerning extension of a period of storage "may be the subject of appeal brought before a court of appeal." (Law No. 115 sec. 7)

**V. QUALITY ASSURANCE MECHANISMS**

**A. AUTHORIZED SITE?** No mention.

**B. AUTHORIZED PRACTITIONER?** No mention.

**C. RECORDKEEPING?** No mention.

**VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR**

**A. INFORMED CONSENT?** The law requires that "measures involving fertilized oocytes of human origin shall be subject to the consent of the oocyte and sperm donors" (Law No. 115 sec.1). The consent requirements are not defined by the legislation.

**B. COUNSELLING?** No mention.

**C. MARITAL STATUS?** No mention.

**VII. PENALTIES**

Yes.

**CCOUNTRY: SWITZERLAND**

- I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP?** A referendum on public demand suggested a constitutional amendment to address the issues raised by assisted procreation (see, Infertility: Medical and Social Choices at 354). The federal government responded by forming a federal commission to study the issues raised by genetics and new reproductive technologies (id.). The Swiss Department of the Interior and the Department of Justice and Police created a commission to discuss the social, legal and ethical impact of new reproductive technologies and to write recommendations for the government (OTA, Biomedical Ethics in U.S. Policy, "Appendix A: International Bioethics Initiatives" p. 51 (1993)).
- II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH?** Yes, effective May 17, 1992, the Federal Constitution of Switzerland was amended to address the issues raised by genetics and assisted procreation (sec.24 novies). The Law states that "[m]an and the environment shall be protected against abuses in the field of procreation and genetic engineering techniques" (24 novies sec.1). Guided by this premise, research is not permitted under the legislation.

The law does not allow assisted procreation techniques to be authorized for research purposes, therefore, no limitations are delineated for conducting research.

**A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** No, research is prohibited. Assisted procreation procedures are only authorized when sterility or the risk of transmitting a serious disease cannot be avoided in any other way (Sec. 2(c)).
2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?** No, the law only authorizes genetic testing with that person's consent or by legal provision. Since the embryo cannot give consent, and there is apparently not a provision authorizing it, a strong argument could be made that the procedure should not be used. On the other hand, one might argue that, since the law authorizes the use of assisted procreation when sterility or the risk of transmitting a serious disease cannot be avoided in any other way (sec. 2(c)), preimplantation screening could be done to assure that this objective is achieved. However, the law was probably not intended to authorize genetic

screening but rather to authorize donation of gametes.

3. **IVF EXPERIMENTATION PROCEDURES?** Yes, if the research would allow the couple to procreate when they otherwise could not.
4. **GENE THERAPY FOR EMBRYOS?** No, the Act prohibits "interventions affecting the genetic heritage of human gametes and embryos" (sec.2(a)).
5. **CRYOPRESERVATION?** No, "[o]nly the number of human ova that may be immediately implanted may be developed as far as the embryo stage, outside the woman's body" (sec.2(c)). This limits the need for cryopreservation and seems to suggest that this procedure is not permissible.
6. **BASIC SCIENTIFIC RESEARCH?** No, the Law prohibits the use of artificial procreation "for research purposes" (sec.2(c)).

**B. ARE ANY TYPES OF PROCEDURES EXPLICITLY PROHIBITED?** No research is permitted. The Amendment only permits methods of artificial procreation to be utilized "when

sterility or the risk of transmission of a serious disease cannot be avoided in any other manner (24 novies (2)(c)). The Amendment also permits that "[o]nly the number of human ova that may be immediately implanted may be developed as far as the embryo stage, outside the woman's body" (id.).

**III. DOES THE LEGISLATION DEFINE:**

- A. "EMBRYO"? No mention.
- B. "EXPERIMENTATION" AND/OR "RESEARCH"? No mention.

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION? No mention.**

- A. COMPOSITION: N/A
- B. AUTHORITY/RESPONSIBILITY: N/A
- C. GRIEVANCE PROCEDURE: N/A

**V. QUALITY ASSURANCE MECHANISMS**

- A. AUTHORIZED SITE? N/A



B. AUTHORIZED PRACTITIONER? N/A

C. RECORDKEEPING? N/A

VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR

A. INFORMED CONSENT? N/A

B. COUNSELLING? N/A

C. MARITAL STATUS? N/A

VII. PENALTIES

No mention.

COUNTRY: THE UNITED KINGDOM

- I. BEFORE THE ENACTMENT OF LEGISLATION, WAS A STUDY OR A REPORT ISSUED BY A NATIONAL COMMISSION, GOVERNMENT AGENCY OR OTHER INTEREST GROUP? The birth of Louise Brown, the first child born as a result of in vitro fertilization, made the possibilities of new reproductive technologies a reality. The new technology caused public anxiety about the possible uses of such technology. (See, Mc K. Norrie, K. "United Kingdom: Legal Regulation of Human Reproduction" in Law Reform and Human Reproduction, ed. McLaren, S., Dartmouth Publishing, 1991.) Public concern about the lack of control over these developments prompted Parliament to explore legislative means of control. (See, id. at 204.) In 1982, the government established The Committee of Inquiry into Human Fertilization and Embryology (the Warnock Committee). In 1984, the Committee published its report. "Warnock is not only the benchmark but the workbench of the present legislation." (Morgan, D. and Lee, R., Blackstone's Guide to the Human Fertilisation and Embryology Act 1990, Blackstone Press, 1991.) The issue of embryo research was central to the considerations of the Warnock Committee. (Law Reform and Human Reproduction at 214.) The Committee recommended "that legislation should provide that research may be carried out on any embryo resulting from in vitro fertilisation, whatever its provenance, up to the end of the

fourteenth day after fertilisation, but subject to all other restrictions as may be imposed by the licensing body."

(Warnock Report, sec. 11.30.)

II. IS THERE A STATUTE WHICH ADDRESSES EMBRYO RESEARCH? Yes,  
the Human Fertilisation Act of 1990. The Human  
Fertilisation Act of 1990 provides:

. . . a statutory framework for the control and supervision of research involving human embryos, . . . [and] for the licensing of certain types of assisted conception practice, namely those which involve the creation of a human embryo outside the body, or partly inside and partly outside, and any treatment service which involves the use of donated gametes (egg and sperm) or donated embryos . . .

(Morgan, D. and Lee, R. Blackstone's Guide to the Human Fertilisation and Embryology Act 1990, Blackstone Press Ltd., 1991).

The limitations on research include the Act's licensing requirement (sec.3(1)), any conditions which may be specified in the license (Schedule 2 sec.3(7)) and the fact that embryos cannot be kept or used beyond the appearance of the primitive streak (sec.3(3)(a)-(d)). The primitive streak is presumed to appear in the embryo no later than 14 days from fertilization not considering any time during which the embryo may have been stored (sec.3 (4)).

**A. DOES THE LEGISLATION PERMIT:**

1. **TWINNING?** Yes. Although the Act is very detailed about the types of research which may or may not be performed, this is a topic not addressed, but because of the Act's permissiveness, this procedure would likely be licensed. Twinning may be seen as "promoting advances in the treatment of infertility" (Schedule 2, sec.3(2)). Activities which are "necessary or desirable" for such a purpose may be authorized for a license.

2. **PREIMPLANTATION GENETIC SCREENING OF EMBRYOS?**

Yes, a license may be granted if the Authority finds "that the proposed activity is necessary or desirable for the purpose of . . . (e)developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation. . . ." (schedule 2 sec.3 (2)(e)). Additionally, this practice may also be licensed under a treatment license which may authorize "practices designed to secure that embryos are in suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose" (Schedule 2 sec.1(1)(d)).

3. **IVF EXPERIMENTAL TECHNIQUES?** Yes, a license may be granted if the Authority finds "that the proposed activity is necessary or desirable for the purpose of . . . promoting advances in the treatment of infertility" (Schedule 2 sec.3(2)(a)).

4. **GENE THERAPY FOR EMBRYOS?** Yes, however,

[a] license [for research] cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations

(Schedule 2 sec.3(4)). (Regulations are discussed in II A 5 and 6) This language would seem to suggest that this technique would be permitted. In addition, a treatment license may authorize this procedure (see, II. A. 2. above and Schedule 2 sec. 1(1)(d)).

5. **CRYOPRESERVATION?** Yes, the law sets forth licensing requirements for storage (sec. 14).

6. **BASIC SCIENTIFIC RESEARCH?** Yes, until 14 days

after fertilization. All activities authorized must be "necessary or desirable" for one of the purposes enunciated in Schedule 2, section 3 and a purpose which may be specified in the regulations (Schedule 2 section 3(2)). One such purpose would include authorization of "projects of research which increase knowledge about the creation developments of embryos, or about disease, or enable such knowledge to be applied" (Schedule 2 sec. 3(3)). This would suggest that basic scientific research may be licensed.

**B. ARE ANY TYPES OF PROCEDURES EXPRESSLY PROHIBITED?** Placing an embryo that is not human in a woman or placing live gametes other than human gametes in a woman is prohibited (sec.3(2)). The Act also enumerates certain procedures that cannot be authorized by a license. These include:

- (a) keeping or using an embryo after the appearance of the primitive streak,
- (b) placing an embryo in any animal,
- (c) keeping or using an embryo in any circumstances in which regulations prohibit keeping or use, or
- (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.

(sec.3(3) (a) - (d))

**III. DOES THE LEGISLATION DEFINE:**

**A. "EMBRYO"? Yes,**

(a) embryo means a live human embryo where fertilisation is complete, and

(b) references to an embryo include an egg in the process of fertilisation and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.

(sec. 1 (1) (a) (b))

**B. "EXPERIMENTATION" AND/OR "RESEARCH"? No mention.**

**IV. IS THERE A REGULATORY BODY RESPONSIBLE FOR IMPLEMENTATION OF THE LEGISLATION? Yes, The Human Fertilisation and Embryology Authority (hereinafter the Authority) (sec. 5).**

**A. COMPOSITION:** The Authority is comprised of a chairman, a deputy chairman and any number of members the Secretary of State appoints (sec. 5(2)). In making appointments, the Secretary must ensure that the proceedings of the Authority will reflect the views of men and women (Schedule I sec.4(2)). The Secretary must appoint at least one medical practitioner registered under the Medical Act of 1983 and at least one person who is or was "concerned with keeping or using gametes or embryos outside the body" (Schedule 1

sec.4(4)).

**B. AUTHORITY/RESPONSIBILITY:** The role of the Authority is defined in section 8 which states that the Authority shall-

(a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matter,

(b) publicise the services provided by the Authority or provided in pursuance of licenses,

(c) provide, to such extent as it considers appropriate, advice and information for persons to whom licenses apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so, and

(d) perform such other functions as may be specified by regulation

(sec.8(a)-(d)). The Authority must appoint one or more committees to carry out the Authority's licensing functions (sec.9(1)).

**C. GRIEVANCE PROCEDURE:** The Act provides for a detailed grievance procedure. If the license committee refuses to grant a license, to change a license so as to name another in place of the person responsible on the license or revokes a license, one may appeal to the Authority (sec.20(1)(2)). Notice must be given to the



committee and the Authority (id.). The appeal process involves a rehearing by the Authority excluding those members of the Authority who participated in the action leading to the appeal (sec. 20(3)). The appellant may appear or be represented as may the licensing committee (sec.20(4)). The Authority must notify the applicant of its decision, and if the decision concerns refusal of a license or refusal to designate another person responsible, the notice must include the reasons for the determination (sec. 20 (5)). If the Authority, pursuant to the procedure described, refuses a license, refuses to name a new person responsible or revokes a license, the person receiving notice of the determination "may appeal to the High Court or, in Scotland, the Court of Session on a point of law" (sec. 21).

## **V. QUALITY ASSURANCE MECHANISMS**

- A. AUTHORIZED SITE?** In order to be granted a license which is necessary to carry out research on embryos, the license committee must be "satisfied that the premises in respect of which the license is to be granted are suitable for the activities" (sec.16 (2)(d)). The Act does not define what is necessary for a site to be considered "suitable".

**B. AUTHORIZED PRACTITIONER?** Another requirement for approval of a license is that the application name the individual who will supervise the activities for which approval is sought (sec.16(2)(a)). This named person must either be the applicant or have given consent to be named in the application, and the committee must be "satisfied that the applicant is a suitable person to hold a license" (sec.16(2)(b)(i)(ii)). Additionally, the Act requires "that the license committee is satisfied that the character, qualification and experience of that individual are such as are required for the supervision of the activity . . . ." (sec.16(2)(c)). The Act sets out several duties of "the person responsible". This individual is responsible for securing:

(a) that the other persons to whom the license applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the license,

(b) that proper equipment is used,

(c) that proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes and embryos that have been allowed to perish,

(d) that suitable practices are used in the course of the activities, and

(e) that the conditions of the license are complied with

(sec.17(1)(a)-(e)).

- C. **RECORDKEEPING?** A general condition for a license is that "proper records shall be maintained in such form as the Authority may specify in directions"(sec.12(d)). The records maintained with regard to a research license must "include such information as the Authority may specify in directions about such matters as the Authority may so specify" (sec.15(2)). Neither of these directives is explicit about the particular information that must be recorded, but the Act does make clear that documentation concerning the activity licensed is necessary.

## VI. REQUIREMENTS AFFECTING DONOR/PROGENITOR

- A. **INFORMED CONSENT?** A general condition, applicable to all licenses granted pursuant to the Act is "that the provisions of Schedule 3" be complied with (sec.12(c)). Schedule 3 is entitled "Consents to Use of Gametes or Embryos" and presents detailed requirements for obtaining informed consent. Consent required under the Act must be in writing ,and to be "effective consent," it cannot have been withdrawn (Schedule 3, sec. 1). Section 6(3), applying to embryos created *in vitro* does not permit such embryos to "be used for any purpose

unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents" (Schedule 3, sec.6(3)).

**B. COUNSELLING?** Counselling is not required under the Act, but before a person gives his or her consent, "he must be given suitable opportunity to receive proper counselling about the implication of taking the proposed steps" (Schedule 3, sec. 3(1)(a)).

**C. MARITAL STATUS?** No mention.

## **VII. PENALTIES**

A penalty of up to ten years imprisonment, a fine or both will be imposed for placing live gametes or a live embryo of another species in the body of a woman, mixing live gametes of an animal or engaging in an activity which cannot be authorized by a license including keeping or using an embryo after development of the primitive streak, placing an embryo in an animal, keeping or using an embryo in a manner prohibited by the regulations or replacing the nucleus of an embryo cell with a nucleus from another person or embryo (sec.41(1)). These activities garner the strictest penalties under the Act. Other punishable offenses include:

creating, keeping or using an embryo without a license (sec.41(2)(a)), or knowingly or recklessly providing false or misleading information concerning a material factor in order to receive a license (sec.41(3)). These offenses are punishable by up to two years imprisonment, a fine or both on conviction and by up to six months imprisonment, a fine or both on summary conviction (sec.41(4)). If the person to whom a license is granted gives or receives compensation, not authorized for the supply or gametes or embryos (sec.41(8)), he will be liable on summary conviction to a prison term not to exceed six months, a fine or both (sec.41(9)).



## **Appendix B**

### **Excerpts of Laws of Other Countries**

## VII. HUMAN REPRODUCTION AND POPULATION POLICIES

**AUSTRALIA (VICTORIA).** The Infertility (Medical Procedures) (Amendment) Act 1987. Dated 1 December 1987.<sup>a</sup> (6 pp.)

Ausl. (Vic.) 90.1

The following are among the principal provisions of this Act, which amends the Infertility (Medical Procedures) Act 1984 (see *IDHL*, 1985, 36, 655, Ausl. (Vic) 85.1). Subsection 5 of Sec. 6 is amended to read as follows:

“(5) Where ova are removed from the body of a woman, a person shall not cause or permit fertilisation of any of those ova to commence outside the body of the woman except—

(a) for the purposes of the implantation of embryos derived from those ova in the womb of that woman or another woman in a relevant procedure in accordance with this Act; or

(b) for the purposes of a procedure to which section 9A applies that is approved and carried out in accordance with that section.

Penalty: 100 penalty units or imprisonment for four years.”

The following new Sec. 9A (Research on process of fertilisation before syngamy) is inserted:

“9A. (1) A procedure to which this section applies is an experimental procedure involving the fertilisation of a human ovum from the point of sperm penetration prior to but not including the point of syngamy.

(2) A procedure to which this section applies—

(a) must be approved by the Standing Review and Advisory Committee before it is commenced; and

(b) must not be carried out unless—

(i) the ova used in the procedure are the ova of a married woman; and

(ii) the woman and her husband are undergoing, in relation to the carrying

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<sup>a</sup> The date of commencement of this Act has been proclaimed as 1 July 1988. — ED.



out of a fertilisation procedure, examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A; and

(iii) the woman and her husband have each consented in writing to the use of the woman's ova in a specific approved experimental procedure; and

(iv) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the woman and her husband have received counselling in relation to the procedure, including counselling in relation to prescribed matters, from an approved counsellor; and

(v) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the carrying out of the procedure is reasonably likely to produce information or establish knowledge indicating procedures (including fertilisation procedures) that might be carried out for the purpose of enabling a woman who has undergone examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A to become pregnant.

(3) A person must not use semen produced by a man (in this sub-section called 'the donor') for the purposes of a procedure to which this section applies unless—

(a) the donor and his spouse are undergoing, in relation to the carrying out of a fertilisation procedure, examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A; and

(b) the donor and (unless he no longer has a spouse) his spouse have each consented in writing to the use of the semen in a specific approved experimental procedure; and

(c) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the donor and the spouse (if any) have received counselling in relation to the procedure including counselling in relation to prescribed matters from an approved counsellor; and

(d) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the carrying out of the procedure is reasonably likely to produce information or establish knowledge indicating procedures (including fertilisation procedures) that might be carried out for the purpose of enabling a woman who has undergone examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A to become pregnant.

Penalty: 25 penalty units or imprisonment for one year."

The following new Sec. 13A (Gamete intra-fallopian transfer and related procedures) is inserted:

"13A. (1) This section applies to any procedure of implanting in the body of a woman (in this section called 'the patient') an ovum, whether produced by that woman or by another woman, and whether or not it has been fertilised outside the body of the patient.

(2) A procedure to which this section applies shall not be carried out at a place other than a hospital that is approved by the Minister as a place at which such procedures may be carried out.

(3) A procedure to which this section applies shall not be carried out unless—

(a) the patient is a married woman;

(b) the patient and her husband have each consented in writing to the carrying out of the procedure and neither the patient nor her husband has withdrawn that consent;

(c) not less than twelve months before the carrying out of the procedure, the patient and her husband had begun to undergo, and have undergone, such examination or treatment by a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) as might reasonably be expected to establish whether or not a procedure other than a fertilisation procedure might cause the woman to become pregnant;

(d) as a result of that examination or treatment, a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) is satisfied that it is reasonably established—

(i) that the patient is unlikely to become pregnant as a result of a procedure other than a procedure to which this section applies; or

(ii) that if the patient were to become pregnant as a result of the fertilisation of an ovum produced by her by semen produced by her husband an undesirable hereditary disorder may be transmitted to a child born as a result of the pregnancy; and

(e) the medical practitioner by whom the procedure is to be carried out is satisfied—

(i) that the patient and her husband have received counselling, including counselling in relation to prescribed matters, from an approved counsellor; and

(ii) that an approved counsellor will be available to give further counsel to the patient and her husband after the procedure is carried out.

(4) Where a consent is given under sub-section (3) (b)—

(a) the document in which the consent is given shall be kept by the hospital in which the procedure to which this section applies is carried out;

(b) a copy shall be given to the patient; and

(c) a copy shall be given to the husband of the patient.

(5) A person shall not use ovum or semen provided by any person (in this section called 'the donor') for the purposes of a procedure to which this section applies unless—

(a) the donor has consented in writing to the use of the ovum or semen in such a procedure and has not withdrawn that consent;

(b) where there is a spouse of the donor, the spouse has consented in writing to the use of the ovum or semen in such a procedure and has not withdrawn that consent; and

(c) the donor and the spouse (if any) of the donor have received counselling from an approved counsellor.

Penalty: 25 penalty units or imprisonment for one year.

(6) A person who gives an ovum or semen that is or may be used in a procedure to which this section applies shall not receive, and another person shall not make or give, any payment or other amount for or in respect of the giving of the ovum or semen other than—

(a) an amount, not exceeding an amount calculated at a prescribed rate, in respect of expenses incurred by that person in travelling to and attending at the place at which the ovum or semen is given; or

(b) an amount in reimbursement of medical expenses incurred by that person in connection with the giving of the ovum or semen.

Penalty applying to this sub-section: 25 penalty units or imprisonment for one year."

In addition, the principal Act is amended by the insertion of the following new definitions: " 'Approved experimental procedure' means an experimental procedure directly related to the alleviation of infertility and approved by the Standing Review and Advisory Committee in accordance with sections 6 (3) and 29 (6) (b) and (ba)"; " 'Syngamy' means the alignment of the mitotic spindle of the chromosomes derived from the pronuclei".

Various references to the "Health Commission" are replaced by "General Manager of the Department of Health".

**AUSTRALIA (VICTORIA).** An Act (No. 10163) relating to the regulation of certain procedures for the alleviation of infertility or to assist conception, to amend the Human Tissue Act 1982 and the Freedom of Information Act 1982, to prohibit agreements relating to surrogate motherhood and for other purposes. Dated 20 November 1984. (The Infertility (Medical Procedures) Act 1984). (23 pp.)

**Ausl. (Vic) 85.1**

The following are among the principal provisions of this Act.

*Part I. Preliminary (Secs. 1-4).* Sec. 2 lays down that the "several provisions of this Act are to come into operation on a day, or on the respective days, to be fixed by proclamation, or successive proclamations, of the Governor in Council published in the *Government Gazette*". Sec. 3 (Interpretation) is substantially reproduced below:

"3. (1) In this Act unless the contrary intention appears—

'Approved counsellor' .....

'Approved hospital' means a scheduled hospital or a private hospital that is for the time being approved under section 7 as a place at which one or more relevant procedures or the procedure of artificial insemination may be carried out.

'Committee' in relation to a scheduled hospital means the committee of management or board of directors or governing body of the scheduled hospital.

'Designated officer' in relation to a hospital means—

(a) a person for the time being appointed under section 8 to be a designated officer for that hospital; or

(b) where at any time, in relation to a hospital, there is no such person, the medical superintendent or, if there is no medical superintendent, the principal executive officer of the hospital or, while the medical superintendent or principal executive officer, as the case may be, is absent from or not on duty at the hospital, a person acting in the place of the medical superintendent or principal executive officer.

*International Digest of Health Legislation, 1985, 36 (3)*

'Fertilization procedure' means—

- (a) a relevant procedure; or
- (b) any other procedure (other than the procedure of artificial insemination) for implanting in the body of a woman—
  - (i) an ovum produced by that woman or by another woman, whether or not it is fertilized outside the body of the first-mentioned woman; or
  - (ii) an embryo derived from an ovum produced by that woman or by another woman whether or not it is fertilized outside the body of the first-mentioned woman.

'Prescribed' means prescribed by this Act or the regulations.

'Private hospital' .....

'Proprietor' in relation to a private hospital includes the owner, the occupier or any person having the management or control of the private hospital.

'Relevant procedure' means a procedure to which section 10, 11, 12 or 13 applies.

'Scheduled hospital' .....

(2) In this Act—

(a) a reference to a married woman includes a reference to a woman—

- (i) who, at the commencement of this section, is living with a man as his wife on a *bona fide* domestic basis although not married to him; and
- (ii) who, before the commencement of this section, had undergone examination or treatment with a view to the carrying out by a medical practitioner of a procedure that, if carried out after that commencement, would be a relevant procedure; and

(b) a reference to the husband of a woman includes, in relation to a woman to whom paragraph (a) applies, a reference to the man with whom the woman is, at the commencement of this section, living as his wife on a *bona fide* domestic basis but does not include a reference to the man (if any) to whom the woman is, at that time, actually married."

*Part II. Regulation of procedures (Secs. 5-18).* The provisions of this Part read as follows:

*"Procedure not to be carried out except in accordance with this Act*

5. (1) Subject to sub-section (2), a person shall not carry out a fertilization procedure.

Penalty: 100 penalty units or imprisonment for four years.

(2) Sub-section (1) does not apply to a person who carries out a relevant procedure in accordance with this Act.

#### *Prohibition of certain procedures*

6. (1) A person shall not carry out a prohibited procedure.

Penalty: 100 penalty units or imprisonment for four years.

*International Digest of Health Legislation, 1985, 36 (3)*

(2) In sub-section (1), 'prohibited procedure' means—

- (a) cloning; or
- (b) a procedure under which the gametes of a man or a woman are fertilized by the gametes of an animal.

(3) A person shall not carry out an experimental procedure other than an experimental procedure approved by the Standing Review and Advisory Committee.

Penalty: 100 penalty units or imprisonment for four years.

(4) In sub-section (3), 'experimental procedure' means a procedure that involves carrying out research on an embryo of a kind that would cause damage to the embryo, would make the embryo unfit for implantation or would reduce the prospects of a pregnancy resulting from the implantation of the embryo.

(5) Where ova are removed from the body of a woman, a person shall not cause or permit those ova to be fertilized outside the body of the woman except for the purposes of the implantation of embryos derived from those ova in the womb of that woman or another woman in a relevant procedure in accordance with this Act.

Penalty: 100 penalty units or imprisonment for four years.

(6) A person shall not carry out a procedure that involves freezing an embryo.

Penalty: 100 penalty units or imprisonment for four years.

(7) Sub-section (6) does not apply to a procedure carried out in an approved hospital that involves freezing an embryo if that procedure is carried out for the purposes of enabling the embryo to be implanted in the womb of a woman at a later date.

(8) Nothing in this Act prevents or inhibits the carrying out in an approved hospital of research on, and the development of techniques for, freezing or otherwise storing ova removed from the body of a woman.

#### *Approval of hospitals*

7. (1) The Committee of a scheduled hospital or the proprietor of a private hospital may make application to the Minister for approval of the hospital as a place at which relevant procedures of the class specified in the application may be carried out.

(2) An application under sub-section (1) shall be made in the form prescribed for relevant procedures to which section 10, 11, 12 or 13 applies or for the procedure of artificial insemination, whichever is applicable.

(3) The Minister may, if he is satisfied that the scheduled hospital or the private hospital has facilities appropriate for the carrying out of relevant procedures of the class specified in the application, by instrument in writing approve the hospital as a place at which procedures of that class may be carried out, subject to such terms and conditions as are specified in the instrument.

(4) The Minister may, at any time by notice in writing given to the Committee of a scheduled hospital or the proprietor of a private hospital vary the terms and conditions to which an approval of that hospital as a place at which relevant procedures of the class specified in the notice may be carried out is subject.

(5) Where the Minister is satisfied that—

- (a) a scheduled hospital;
- (b) the Committee or designated officer of a scheduled hospital;

*International Digest of Health Legislation, 1985, 36 (3)*

- (c) a private hospital; or
- (d) the proprietor or designated officer of a private hospital—

has committed an offence against this Act or the regulations or has failed to comply with a term or condition to which the approval of that hospital under this section is subject, the Minister may, by notice in writing given to the Committee of the scheduled hospital or proprietor of the private hospital, cancel the approval of the hospital as a place at which relevant procedures of the class specified in the notice may be carried out.

(6) Where the approval of a scheduled hospital or a private hospital is cancelled under this section, the Minister may give such directions as he determines in relation to the control and management of the hospital, the continuation of treatment of patients, use of gametes held by the hospital for relevant procedures (including directions for transfer of gametes to an approved hospital), keeping of records and other relevant matters.

(7) In this section, a reference to a relevant procedure includes a reference to the procedure of artificial insemination.

#### *Designated officer*

8. (1) The Committee of a scheduled hospital, being an approved hospital, or the proprietor of a private hospital, being an approved hospital, may, by instrument in writing, appoint such persons, being medical practitioners or other persons, as the Committee or proprietor considers appropriate to be, for the purposes of this Act, designated officers for the hospital.

(2) The power under this section to appoint a person as a designated officer includes the power, by instrument in writing, to remove a person so appointed.

#### *Approval of counsellors*

9. (1) A person may make application to the Minister for approval as a counsellor for the purposes of this Act.

(2) An application under sub-section (1) shall be in the prescribed form and shall specify—

- (a) each approved hospital where the relevant procedures in relation to which the applicant proposes to give counsel may be carried out; and
- (b) whether the applicant seeks approval in relation to giving counsel—

- (i) to a woman in relation to whom a relevant procedure specified in the approval may be, or has been, carried out;
- (ii) to the husband of such a woman;
- (iii) to a person who may give gametes for use in a relevant procedure;
- (iv) to the spouse of such a person; or
- (v) to two or more of the classes of person specified in sub-paragraphs (i) to (iv).

(3) The Minister may by instrument in writing approve an applicant under this section as a counsellor for the purposes of this Act in relation to giving counsel to the classes of person specified in the instrument and may, by instrument in writing, vary or cancel that approval.

(4) Where the Minister approves a person as a counsellor under this section or varies or cancels that approval, he shall give notice in writing to each approved hospital of that approval, variation or cancellation.

(5) A reference in this Act to an approved counsellor in relation to giving counsel to a particular person means a person approved for the time being under this section as a counsellor for the purposes of this Act in relation to giving counsel to persons of the same class as that particular person.

(6) The Minister shall from time to time and at least once in each year cause to be published in the *Government Gazette* the names of persons approved for the time being under this Act as counsellors for the purpose of giving counsel to specified classes of persons.

*Procedure of in vitro fertilization—no donors*

10. (1) This section applies to the procedure of implanting in the womb of a woman an embryo derived from an ovum produced by her and fertilized outside her body by semen produced by her husband.

(2) A procedure to which this section applies shall not be carried out at a place other than a hospital that is approved by the Minister as a place at which such procedures may be carried out.

(3) A procedure to which this section applies shall not be carried out unless—

(a) the woman in relation to whom the procedure is carried out is a married woman;

(b) the woman and her husband each consents in writing to the carrying out of the procedure;

(c) not less than twelve months before the carrying out of the procedure, the woman and her husband had begun to undergo, or have undergone, such examination or treatment by a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) as might reasonably be expected to establish whether or not a procedure other than a fertilization procedure might cause the woman to become pregnant;

(d) as a result of that examination or treatment, a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) is satisfied that it is reasonably established that the woman is unlikely to become pregnant as the result of a procedure other than a fertilization procedure; and

(e) the medical practitioner by whom the procedure is to be carried out is satisfied—

(i) that the woman and her husband have received counselling, including counselling in relation to prescribed matters, from an approved counsellor;

(ii) that an approved counsellor will be available to give further counsel to the woman and her husband after the procedure is carried out.

*Procedure of in vitro fertilization—male donors*

11. (1) This section applies to the procedure of implanting in the womb of a woman an embryo derived from an ovum produced by her and fertilized outside her body by semen produced by a man other than her husband.



(2) A procedure to which this section applies shall not be carried out at a place other than a hospital that is approved by the Minister as a place at which such procedures may be carried out.

(3) A procedure to which this section applies shall not be carried out unless—

(a) the woman in relation to whom the procedure is carried out is a married woman;

(b) the woman and her husband have each consented in writing to the carrying out of a procedure to which this section applies and neither the woman nor her husband has withdrawn that consent;

(c) not less than twelve months before the carrying out of the procedure, the woman and her husband had begun to undergo, and have undergone, such examination or treatment by a medical practitioner other than the medical practitioner by whom the procedure is to be carried out as might reasonably be expected to establish whether or not a procedure other than a fertilization procedure might cause the woman to become pregnant;

(d) as a result of that examination or treatment, a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) is satisfied that it is reasonably established—

(i) that the woman is unlikely to become pregnant as the result of a procedure other than a fertilization procedure; or

(ii) that if the woman were to become pregnant as a result of the fertilization of an ovum produced by her by semen produced by her husband an undesirable hereditary disorder may be transmitted to a child born as the result of the pregnancy;

(e) the medical practitioner by whom the procedure is to be carried out is satisfied—

(i) that the woman and her husband have received counselling, including counselling in relation to prescribed matters, from an approved counsellor; and

(ii) that an approved counsellor will be available to give further counsel to the woman and her husband after the procedure is carried out.

(4) Where a consent is given under paragraph (b) of sub-section (3)—

(a) the document in which the consent is given shall be kept by the hospital in which the procedure to which this section applies is carried out;

(b) a copy shall be given to the woman in relation to whom the procedure is to be carried out; and

(c) a copy shall be given to the husband of the woman.

(5) A person shall not use semen produced by a man (in this section called 'the donor') for the purposes of a procedure to which this section applies unless—

(a) the donor has consented in writing to the use of the semen in such a procedure and has not withdrawn that consent;

(b) where there is a spouse of the donor, the spouse has consented in writing to the use of the semen in such a procedure and has not withdrawn that consent; and

(c) the donor and the spouse (if any) of the donor have received counselling from an approved counsellor.

Penalty: 25 penalty units or imprisonment for one year.

(6) A man who gives semen that is or may be used in a procedure to which this section applies shall not receive, and another person shall not make or give, any payment or other amount for or in respect of the giving of the semen other than—

(a) an amount, not exceeding an amount calculated at a prescribed rate, in respect of expenses incurred by that man in travelling to and attending all the place at which the semen is given; or

(b) an amount in reimbursement of medical expenses incurred by that man in connexion with the giving of the semen.

Penalty applying to this sub-section: 25 penalty units or imprisonment for one year.

*Procedure of in vitro fertilization—female donors*

12. (1) This section applies to the procedure of implanting in the womb of a woman (in this section called 'the patient') an embryo derived from an ovum produced by another woman (in this section called 'the donor') and fertilized outside the body of the patient and outside the body of the donor by semen produced by the husband of the patient.

(2) A procedure to which this section applies shall not be carried out a place other than a hospital that is approved by the Minister as a place at which such procedures may be carried out.

(3) A procedure to which this section applies shall not be carried out unless—

(a) the patient is a married woman;

(b) the patient and her husband each consented in writing to the carrying out of the procedure and neither the patient nor her husband has withdrawn that consent;

(c) not less than twelve months before the carrying out of the procedure, the patient and her husband had begun to undergo, and have undergone, such examination or treatment by a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) as might reasonably be expected to establish whether or not a procedure other than a fertilization procedure might cause the patient to become pregnant;

(d) as a result of that examination or treatment, a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) is satisfied that it is reasonably established—

(i) that the patient is unlikely to become pregnant as the result of a procedure other than a fertilization procedure; or

(ii) that if the patient were to become pregnant as a result of the fertilization of an ovum produced by her, an undesirable hereditary disorder may be transmitted to a child born as a result of the pregnancy; and

(e) the medical practitioner by whom the procedure is to be carried out is satisfied—

(i) that the patient and her husband have received counselling, including counselling in relation to prescribed matters, from an approved counsellor; and

(ii) that an approved counsellor will be available to give further counsel to the patient and her husband after the procedure is carried out.

## (4) Where a consent is given under paragraph (b) of sub-section (3)—

- (a) the document in which the consent is given shall be kept by the hospital in which the procedure to which this section applies is carried out;
- (b) a copy shall be given to the patient; and
- (c) a copy shall be given to the husband of the patient.

## (5) A person shall not in a procedure to which this section applies, use an ovum removed from a woman (in this sub-section called 'the donor') unless, before the ovum was removed—

- (a) the donor consented in writing to the use of the ovum in a procedure to which this section applies, being a procedure to be carried out in relation to another woman, and has not withdrawn that consent;
- (b) the husband (if any) of the donor consented in writing to the use of the ovum in such a procedure and has not withdrawn that consent; and
- (c) the donor and her husband (if any) received counselling from an approved counsellor.

Penalty: 25 penalty units or imprisonment for one year.

## (6) A woman who gives an ovum that is or may be used in a procedure to which this section applies shall not receive, and another person shall not make or give any payment or other amount for or in respect of the giving of the ovum other than—

- (a) an amount, not exceeding an amount calculated at a prescribed rate, in respect of expenses incurred by that woman in travelling to and attending at the place at which the ovum is given; or
- (b) an amount in reimbursement of medical expenses incurred by that woman in connexion with the giving of the ovum.

Penalty applying to this sub-section: 25 penalty units or imprisonment for one year.

*Procedure of in vitro fertilization—male and female donors*

13. (1) This section applies to the procedure of implanting in the womb of a woman (in this section called 'the patient') an embryo derived from an ovum produced by another woman (in this section called 'the donor') and fertilized outside the body of the patient and outside the body of the donor by semen produced by a man other than the husband of the patient.

(2) A procedure to which this section applies shall not be carried out at a place other than a hospital that is approved by the Minister as a place at which such procedures may be carried out.

## (3) A procedure to which this section applies shall not be carried out unless—

- (a) the patient is a married woman;
- (b) the patient and her husband each consented in writing to the carrying out of the procedure and neither the patient nor the husband has withdrawn that consent;
- (c) not less than twelve months before the carrying out of the procedure, the patient and her husband had begun to undergo, and have undergone, such examination or treatment by a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) as might reasonably

be expected to establish whether or not a procedure other than a fertilization procedure might cause the patient to become pregnant;

(d) as a result of that examination or treatment, a medical practitioner (other than the medical practitioner by whom the procedure is to be carried out) is satisfied that it is reasonably established—

(i) that the patient is unlikely to become pregnant as the result of a procedure other than a procedure to which this section applies; or

(ii) that if the patient were to become pregnant as a result of the fertilization of an ovum produced by her or if semen produced by her husband were used to fertilize an ovum as a result of which a woman becomes pregnant, an undesirable hereditary disorder may be transmitted to a child born as the result of the pregnancy;

(e) where more than one embryo is used in the procedure, the gametes from which each embryo was derived were produced by the same two persons; and

(f) the medical practitioner by whom the procedure is to be carried out is satisfied—

(i) that the patient and her husband have received counselling, including counselling in relation to prescribed matters, from an approved counsellor; and

(ii) that an approved counsellor will be available to give further counsel to the patient and her husband after the procedure is carried out.

(4) Where a consent is given under paragraph (b) of sub-section (3)—

(a) the document in which the consent is given shall be kept by the hospital in which the procedure to which this section applies is carried out.

(b) a copy shall be given to the patient; and

(c) a copy shall be given to the husband of the patient.

(5) A person shall not use semen produced by a man (in this sub-section called 'the donor') for the purposes of a procedure to which this section applies unless—

(a) the donor has consented in writing to the use of the semen in such a procedure and has not withdrawn that consent;

(b) where there is a spouse of the donor, the spouse has consented to the use of the semen in such a procedure and has not withdrawn that consent; and

(c) the donor and the spouse (if any) of the donor have received counselling from an approved counsellor.

Penalty: 50 penalty units or imprisonment for two years.

(6) A person shall not, in a procedure to which this section applies, use an ovum removed from a woman (in this sub-section called 'the donor') unless, before the ovum was removed—

(a) the donor consented in writing to the use of the ovum in a procedure to which this section applies, being a procedure to be carried out in relation to another woman, and has not withdrawn that consent;

(b) the husband (if any) of the donor consented in writing to the use of the ovum in such a procedure and has not withdrawn that consent; and

(c) the donor and her husband (if any) received counselling from an approved counsellor.

Penalty: 50 penalty units or imprisonment for two years.

(7) A person who gives gametes that are or may be used in a procedure to which this section applies shall not receive, and another person shall not make or give, any payment or other amount for or in respect of the giving of the gametes other than—

(a) an amount, not exceeding an amount calculated at a prescribed rate, in respect of expenses incurred by that person in travelling to and attending at the place at which the gametes are given; or

(b) an amount in reimbursement of medical expenses incurred by that person in connexion with the giving of the gametes.

Penalty: 50 penalty units or imprisonment for two years.

(8) Where, for the purposes of a relevant procedure, an embryo has been derived from gametes produced by a married woman and her husband and is not required for the purposes of a relevant procedure carried out in relation to that married woman, the embryo may, subject to and in accordance with this section, be used in a procedure to which this section applies to be carried out in relation to another married woman where—

(a) before the embryo was derived from the gametes produced by the first-mentioned married woman and her husband each consented in writing to the use of such an embryo for a procedure carried out in relation to another married woman and neither the first-mentioned married woman nor her husband had withdrawn that consent; and

(b) the first-mentioned married woman and her husband had received counselling from an approved counsellor in relation to that consent.

(9) A married woman and her husband who give an embryo that is or may be used in a procedure to which this section applies shall not receive, and another person shall not make or give, any payment or other amount for or in respect of the giving of the embryo.

Penalty applying to this sub-section: 75 penalty units or imprisonment for three years.

*Authority for use of embryo in alternative relevant procedure*

14. (1) Where, after an embryo has been derived from an ovum produced by a woman and fertilized outside her body for the purposes of a relevant procedure to be carried out in relation to her or another woman, the embryo cannot be implanted in the body of that woman whether by reason of her death or an accident or injury causing her to be incapable of receiving the implantation or otherwise—

(a) the embryo shall be made available, in accordance with the consent of the persons who produced the gametes from which the embryo was derived, for use in a relevant procedure carried out in relation to another woman; or

(b) where those consents cannot be obtained because the persons are dead or cannot be found, the Minister shall direct the designated officer of the approved hospital where the embryo is stored to ensure that the embryo is made available for use in a relevant procedure.

(2) Where the Minister gives a direction to a designated officer under sub-section (1) in relation to the use of an embryo in a relevant procedure—

(a) the designated officer shall comply with the directions; and

(b) the provisions of section 13 (other than sub-sections (5), (6) and (8)) apply to the relevant procedure.

*Withdrawal of consent to use of gametes*

15. (1) Where—

- (a) a person who has given gametes for use in a specified relevant procedure; or
- (b) the spouse of such a person—

withdraws consent to the use of the gametes in that procedure by notice in writing given to the designated officer of the approved hospital at which the gametes were given, the designated officer shall—

- (c) unless the person or spouse has consented to the use of the gametes in any other relevant procedure; or
- (d) the gametes have been used in a relevant procedure—

forthwith on receiving the notice, destroy the gametes or cause them to be destroyed.

(2) A person shall not incur any civil or criminal liability by reason only of the use in a relevant procedure of gametes given by a person who withdraws consent to the use unless where consent was withdrawn before that use the person knew or ought reasonably to have known of the withdrawal of the consent.

*Use of gametes of identified donors*

16. Where, for the purposes of a relevant procedure to be carried out in relation to a married woman, the married woman and her husband request in writing that gametes to be given by a specified person (in this section called 'the donor') be used, nothing in this Act prevents the use of those gametes in a relevant procedure carried out in accordance with this Act if the designated officer of the approved hospital where the procedure is to be carried out has certified in writing—

- (a) that the same criteria have been applied to the examination of the suitability of the gametes for use in that procedure as would be applied to the selection of any other gametes for use in such a procedure; and
- (b) that the married woman, her husband and the donor have received counselling (in addition to any other counselling required under this Act) in respect of the use of the gametes of the donor in the procedure.

*Artificial insemination*

17. (1) A person, who is not a medical practitioner shall not carry out a procedure of artificial insemination.

Penalty: 25 penalty units or imprisonment for one year.

(2) Sub-section (1) does not apply to a person who carries out a procedure of artificial insemination in an approved hospital.

*Artificial insemination—counselling*

18. A person shall not carry out a procedure of artificial insemination unless the woman in relation to whom the procedure is carried out and her husband have

received counselling, including counselling in relation to prescribed matters, from an approved counsellor.

Penalty: 10 penalty units."

*Part III. Records (Secs. 19-23).* The provisions of this Part read as follows:

*"Records to be kept by approved hospitals"*

19. (1) The Committee of a scheduled hospital, being an approved hospital and the proprietor of a private hospital, being an approved hospital, shall maintain or cause to be maintained a register for the purposes of this Part.

(2) The designated officer of an approved hospital shall, in respect of things done or that may be done in that hospital relating to relevant procedures (whether or not carried out in that hospital) enter in the register maintained by the Committee or proprietor of that hospital under sub-section (1)—

- (a) the prescribed particulars of each person who gives gametes that are or may be used in a relevant procedure;
- (b) the prescribed particulars of consents given by persons for the purposes of relevant procedures;
- (c) the prescribed particulars of amounts paid to each person who gives gametes that are or may be used in a relevant procedure in respect of expenses incurred in connexion with the giving of the gametes;
- (d) where gametes are destroyed, the prescribed particulars of the destruction;
- (e) where an embryo is derived from the fertilization of an ovum, the prescribed particulars relating to that embryo;
- (f) where an embryo is disposed of (otherwise than by implantation in the womb of a woman), the prescribed particulars of that disposal;
- (g) the prescribed particulars of the use of gametes in relevant procedures; and
- (h) where a child is born as a result of a pregnancy occurring as a result of a relevant procedure carried out in the hospital, the prescribed particulars, so far as they are or ought reasonably to be known to the designated officer, of the birth of the child including particulars of any physical abnormalities identified at or about the time of the birth and of the parents of the child and of donors of gametes used in the procedure.

(3) Where a child is born as a result of a pregnancy occurring as a result of a relevant procedure carried out in an approved hospital, the designated officer of the approved hospital shall send or cause to be sent to the Health Commission a copy of—

- (a) the particulars entered in the register under paragraph (a) of sub-section (2) of each person who gave gametes that were used in the procedure; and
- (b) the particulars entered in the register under paragraph (h) of sub-section (2) relating to that birth.

(4) Where a relevant procedure is carried out in an approved hospital and gametes used in the procedure were given in another approved hospital—

- (a) the designated officer of the approved hospital in which the gametes were given shall give to the designated officer of the other approved hospital a

copy of the prescribed particulars relating to the gametes, and of consents relating to those gametes, required to be entered in a register under this section; and

(b) the designated officer of the approved hospital in which the relevant procedure is carried out shall enter those prescribed particulars in the register maintained under this section by the Committee or proprietor of that approved hospital.

(5) In this section, a reference to a relevant procedure includes a reference to a procedure of artificial insemination.

Penalty: 5 penalty units.

*Disclosure of non-identifying information to donors and patients*

20. (1) Before a relevant procedure is carried out in relation to a married woman, the designated officer of the approved hospital in which the procedure is to be carried out shall give in writing to the married woman particulars of each person (other than particulars by which that person may be identified) who gives gametes that may be used in the procedure.

(2) The designated officer of an approved hospital shall offer or cause to be offered in writing to each person who gives gametes that may be used in a relevant procedure to give particulars of each married woman in relation to whom the procedure may be carried out (other than particulars by which the married woman or her husband may be identified) and, where the person asks in writing to be given those particulars, the designated officer shall give the person those particulars or, where the gametes have been given to another approved hospital, inform the person of the name of the hospital from which those particulars may be obtained.

(3) A person who gives gametes that may be used in a relevant procedure may in writing ask the designated officer of the approved hospital where the gametes may be or have been used to give the person particulars of each child born as the result of pregnancy occurring as the result of the use of the gametes (other than particulars by which the child may be identified).

*Records of artificial insemination not carried out in approved hospital*

21. Where a procedure of artificial insemination is carried out by a medical practitioner, the medical practitioner shall keep a written record of—

(a) the prescribed particulars of the man who gave the semen used in the procedure; and

(b) where a child is born as the result of a pregnancy occurring as a result, or as a possible result, of the procedure, the prescribed particulars of the birth of the child—

and, where a child is so born, shall send to the Health Commission a copy of that written record.

*Health Commission to keep central register*

22. (1) The Health Commission shall maintain or cause to be maintained a register containing the particulars copies of which are sent to the Health Commission under section 19 or 21.



## (2) The regulations—

(a) may prescribe the classes of persons who may be given access to specified parts of the register maintained under this section and to specified information contained in that register and the circumstances in which and conditions subject to which persons included in those classes of persons may have that access; or

(b) may provide that the Minister or the Secretary of the Health Commission may, subject to sub-section (3), permit specified persons or specified classes of persons to have access to specified parts of that register and to specified information contained in that register under such circumstances and subject to such conditions as the Minister or the Secretary determines.

(3) The Minister or the Secretary of the Health Commission shall not under regulations made under this section permit a person to have access to information that identifies another person or from which another person may be identified unless that other person, or a person acting on behalf of that other person, has consented in writing to the permitting of access to that information.

(4) The Health Commission shall, before 30 September in each year after the year in which this section comes into operation, submit to the Minister of Health a report—

(a) on proposals for regulations to be made under sub-section (2); and

(b) where regulations have been made under sub-section (2), the manner of the operation of those regulations.

(5) The Minister of Health shall cause a report made to him under sub-section (4) to be laid before both Houses of Parliament within three weeks after it is received or, if Parliament is not then sitting, within three weeks after the next assembling of Parliament.

*Information not to be disclosed*

23. (1) Except as provided in this Act and subject to this section, a person shall not, except in the performance of a duty or function under this Act, disclose to another person any particulars required to be entered in a register maintained under section 19 or 22, being particulars known to that person in the capacity as a designated officer of an approved hospital, an approved counsellor, a medical practitioner or person employed or engaged in an approved hospital or a person employed in the Health Commission.

Penalty: 50 penalty units.

(2) A person born as the result of a pregnancy occurring as the result of the carrying out of a relevant procedure may make application to the Health Commission for information about the donor of gametes from which the embryo used in the relevant procedure was derived.

(3) Where the Health Commission receives an application under sub-section (2), the Health Commission shall give or cause to be given to the applicant such information (other than information from which a donor of gametes may be identified) as the Health Commission has in its possession or under its control."

*Part IV. General (Secs. 24-29).* Sec. 24 provides for conscientious objection to participation in relevant procedures. Secs. 25 (Gametes of persons under eight-

een not to be used in procedures) and 26 (Prohibition of certain procedures) read as follows:

“25. (1) It is not lawful to use in a relevant procedure gametes produced by a child.

Penalty: 50 penalty units or imprisonment for two years.

(2) In sub-section (1), ‘child’ means a person who—

- (a) has not attained the age of eighteen years; and
- (b) is not married.

26. A person shall not carry out a procedure of artificial insemination of a woman or a relevant procedure where the semen used for the artificial insemination or relevant procedure was produced by more than one man.

Penalty: 50 penalty units or imprisonment for two years.”

Secs. 27 and 28 deal with false or misleading statements, and offences, respectively. Sec. 29 provides for the establishment of a Standing Review and Advisory Committee, the membership of which is to consist of: a person holding a qualification in the study of philosophy; two medical practitioners; two persons representing religious bodies; a person qualified in social work; a legal practitioner; and a person qualified as a teacher, with an interest in community affairs. The members are to be appointed by the Minister. Subsections 6-11 read as follows:

“(6) The functions of the Committee are—

- (a) to advise the Minister in relation to infertility and procedures for alleviating infertility;
- (b) to consider requests for approval of and, if it sees fit, to approve, experimental procedures for the purposes of section 6(3); and
- (c) to advise and report to the Minister on any matters relating to infertility and procedures for alleviating infertility and any other associated matters referred to it by the Minister.

(7) In the exercise of its functions, the Committee—

- (a) shall have regard to the principle that childless couples should be assisted in fulfilling their desire to have children;
- (b) shall ensure that the highest regard is given to the principle that human life shall be preserved and protected at all times; and
- (c) shall have regard to the spirit and intent of the several provisions of this Act.

(8) Where the Committee approves an experimental procedure for the purposes of section 6 (3), the Committee shall forthwith report the approval to the Minister.

(9) The Committee shall make an annual report to the Minister on—

- (a) programmes in Victoria under which relevant procedures were carried out in approved hospitals during the year to which the report relates; and
- (b) particulars of each programme carried out in each approved hospital in that year including the number of relevant procedures carried out and the number of participants in each programme.

(10) The Committee may from time to time make such recommendations to the Minister on its activities and on its own operation and composition as it sees fit.

(11) The Committee may collate such information relating to and keep such records of programmes and procedures to which this Act relates as it sees fit and may collate information relating to, and keep records of, similar programmes and procedures carried out in another State or in a Territory."

*Part V. Surrogate motherhood (Sec. 30).* This section reads as follows:

"30. (1) In this section, a reference to a woman who acts, or agrees with another person or other persons to act, as a surrogate mother is a reference to a woman who has entered into, or enters into, a contract, agreement or arrangement with that other person or those other persons, whether formal or informal, and whether or not for payment or reward under which the woman agrees—

(a) to become pregnant, or to seek or attempt to become pregnant, with the intention that a child born as the result of the pregnancy become and be treated, whether by adoption, agreement or otherwise, as the child of that other person or of those other persons; or

(b) being pregnant, that a child born as the result of the pregnancy become and be treated, whether by adoption, agreement or otherwise, as the child of that other person or those other persons.

(2) A person shall not—

(a) publish, or cause to be published, a statement or an advertisement, notice or other document that—

(i) is intended or likely to induce a person to agree to act as a surrogate mother;

(ii) seeks or purports to seek a woman who is willing to agree to act as a surrogate mother; or

(iii) states or implies that a woman is willing to agree to act as a surrogate mother;

(b) make, give or receive, or agree to make, give or receive, a payment or reward for or in consideration of the making of a contract, agreement or arrangement under which a woman agrees to act as surrogate mother; or

(c) receive or agree to receive a payment or reward in consideration for acting, or agreeing to act, as a surrogate mother.

Penalty: 50 penalty units or imprisonment for two years.

(3) A contract or agreement (whether made before or after the commencement of this section) under which a woman agrees with another person or other persons to act as a surrogate mother is void."

*Part VI. Application for review (Sec. 31).* Provision is made for the review of decisions by the Administrative Appeals Tribunal.

*Part VII. Regulations (Sec. 32).* This Section reads as follows:

"32. (1) The Governor in Council may make regulations for or with respect to prescribing any matter or thing authorized or required to be prescribed for the purposes of this Act and in particular for or with respect to—

(a) prescribing the particulars to be recorded in a register maintained by an approved hospital including particulars of the previous medical and social history of a person who gives gametes for use in a relevant procedure; and

(b) prescribing matters in relation to which counselling is required before a relevant procedure of a specified class is carried out.

(2) The regulations shall be subject to disallowance by Parliament."

*Part VIII. Consequential amendments (Secs. 33-34).* Sec. 33 (Sale of gametes prohibited) provides for a consequential amendment to the Human Tissue Act 1982 (see *IDHL*, 1984, 35, 335, *Ausl. (Vic)* 84.4).

*See also* p. 646 (*Den.* 85.3), p. 743 (*USA* 85.44), p. 744 (*USA* 85.47), p. 570 (*USA* 85.70)

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## 2 | **Extracts from the Infertility (Medical Procedures) Act 1984 (Victoria)**

(as amended, 1987)

### **Interpretation.**

3. (1) In this Act unless the contrary intention appears—

**“Approved experimental procedure”** means an experimental procedure directly related to the alleviation of infertility and approved by the Standing Review and Advisory Committee in accordance with sections 6(3) and 29(6)(b) and (ba).

**“Fertilization procedure”** means—

- (a) a procedure to which section 10, 11, 12, 13, or 13A applies; or
- (b) any other procedure (other than the procedure of artificial insemination) for implanting in the body of a woman—
  - (i) an ovum produced by that woman or by another woman, whether or not it is fertilized outside the body of the first-mentioned woman; or
  - (ii) an embryo derived from an ovum produced by that woman or by another woman whether or not it is fertilized outside the body of the first-mentioned woman.

**“Syngamy”** means the alignment on the mitotic spindle of the chromosomes derived from the pronuclei.

**Procedure not be carried out except in accordance with this Act.**

5. (1) Subject to sub-section (2), a person shall not carry out a fertilization procedure.

Penalty: 100 penalty units or imprisonment for four years.

(2) Sub-section (1) does not apply to a person who carries out a relevant procedure in accordance with this Act.

**Prohibition of certain procedures.**

6. (1) A person shall not carry out a prohibited procedure.

Penalty: 100 penalty units or imprisonment for four years.

(2) In sub-section (1), “prohibited procedure” means—

(a) cloning; or

(b) a procedure under which the gametes of a man or a woman are fertilized by the gametes of an animal.

(3) A person shall not carry out an experimental procedure other than an experimental procedure approved by the Standing Review and Advisory Committee.

Penalty: 100 penalty units or imprisonment for four years.

(4) In sub-section (3), “experimental procedure” means a procedure that involves carrying out research on an embryo of a kind that would cause damage to the embryo, would make the embryo unfit for implantation or would reduce the prospects of a pregnancy resulting from the implantation of the embryo.

(5) Where ova are removed from the body of a woman, a person shall not cause or permit fertilisation of any of those ova to commence outside the body of the woman except—

(a) for the purposes of the implantation of embryos derived from those ova in the womb of that woman or another woman in a relevant procedure in accordance with this Act; or

(b) for the purposes of a procedure to which section 9A applies that is approved and carried out in accordance with that section.

Penalty: 100 penalty units or imprisonment for four years.

(6) A person shall not carry out a procedure that involves freezing an embryo.

Penalty: 100 penalty units or imprisonment for four years.

(7) Sub-section (6) does not apply to a procedure carried out in an approved hospital that involves freezing an embryo if that procedure is carried

out for the purposes of enabling the embryo to be implanted in the womb of a woman at a later date.

(8) Nothing in this Act prevents or inhibits the carrying out in an approved hospital of research on, and the development of techniques for, freezing or otherwise storing ova removed from the body of a woman . . .

**Research on process of fertilisation before syngamy.**

9A. (1) A procedure to which this section applies is an experimental procedure involving the fertilisation of a human ovum from the point of sperm penetration prior to but not including the point of syngamy.

(2) A procedure to which this section applies—

(a) must be approved by the Standing Review and Advisory Committee before it is commenced; and

(b) must not be carried out unless—

(i) the ova used in the procedure are the ova of a married woman; and

(ii) the woman and her husband are undergoing, in relation to the carrying out of a fertilisation procedure, examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A; and

(iii) the woman and her husband have each consented in writing to the use of the woman's ova in a specific approved experimental procedure; and

(iv) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the woman and her husband have received counselling in relation to the procedure, including counselling in relation to prescribed matters, from an approved counsellor; and

(v) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the carrying out of the procedure is reasonably likely to produce information or establish knowledge indicating procedures (including fertilisation procedures) that might be carried out for the purpose of enabling a woman who has undergone examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A to become pregnant.

(3) A person must not use semen produced by a man (in this subsection called "the donor") for the purposes of a procedure to which this section applies unless—

- (a) the donor and his spouse are undergoing, in relation to the carrying out of a fertilisation procedure, examination or treatment of a kind referred to in section 10, 11, 12, 13 or 13A; and
- (b) the donor and (unless he no longer has a spouse) his spouse have each consented in writing to the use of the semen in a specific approved experimental procedure; and
- (c) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the donor and the spouse (if any) have received counselling in relation to the procedure including counselling in relation to prescribed matters from an approved counsellor; and
- (d) a medical practitioner by whom or on whose behalf the procedure is to be carried out is satisfied that the carrying out of the procedure is reasonably likely to produce information or establish knowledge indicating procedures (including fertilisation procedures) that might be carried out for the purpose of enabling a woman who has undergone examination or treatment of a kind referred to in section 10, 11, 12, 13, or 13A to become pregnant.

Penalty: 25 penalty units or imprisonment for one year.

...

#### **Standing Review and Advisory Committee.**

29. (1) There shall be a Standing Review and Advisory Committee consisting of—

- (a) a person holding a qualification in the study of philosophy;
- (b) two medical practitioners;
- (c) two persons representing religious bodies;
- (d) a person qualified in social work;
- (e) a legal practitioner; and
- (f) a person qualified as a teacher with an interest in community affairs—

appointed by the Minister, one of whom shall be appointed as chairman.

(2) A member of the Committee shall hold office for such period as is specified in the instrument of appointment and shall be eligible for re-appointment.

(3) A member of the Committee may be removed from office at any time by the Minister.



(4) A member of the Committee is not, by reason only of being a member, subject to the *Public Service Act 1974*.

(5) Subject to this section, the Committee may regulate its proceedings in such manner as it thinks fit.

(6) The functions of the Committee are—

- (a) to advise the Minister in relation to infertility and procedures for alleviating infertility;
- (b) to consider requests for approval of and, if it sees fit, to approve, experimental procedures for the purposes of section 6 (3);
- (ba) to consider requests for approval of and, if it sees fit, to approve a procedure to which section 9A applies; and
- (c) to advise and report to the Minister on any matters relating to infertility and procedures for alleviating infertility and any other associated matters referred to it by the Minister.

(7) In the exercise of its functions, the Committee—

- (a) shall have regard to the principle that childless couples should be assisted in fulfilling their desire to have children;
- (b) shall ensure that the highest regard is given to the principle that human life shall be preserved and protected at all times; and
- (c) shall have regard to the spirit and intent of the several provisions of this Act.

(8) Where the Committee approves an experimental procedure for the purposes of section 6 (3), or a procedure to which section 9A applies the Committee shall forthwith report the approval to the Minister.

(9) The Committee shall make an annual report to the Minister on—

- (a) programmes in Victoria under which relevant procedures were carried out in approved hospitals during the year to which the report relates; and
- (b) particulars of each programme carried out in each approved hospital in that year including the number of relevant procedures carried out and the number of participants in each programme.

(10) The Committee may from time to time make such recommendations to the Minister on its activities and on its own operation and composition as it sees fit.

(11) The Committee may collate such information relating to and keep such records of, programmes and procedures to which this Act relates as it sees fit and may collate information relating to, and keep records of, similar programmes and procedures carried out in another State or in a Territory.

(12) The Minister shall cause—

- (a) each report made by the Committee under sub-section (8); and
- (b) each annual report made by the Committee under sub-section (9)—

to be laid before each House of Parliament within 14 sitting days after the Minister receives the report or, if a House of Parliament is not then sitting, within 14 days after the next meeting of that House.

## VII. HUMAN REPRODUCTION AND POPULATION POLICIES

**AUSTRIA.** Federal Law of 1992 (Serial No. 275) regulating medically assisted procreation (the Reproductive Medicine Law), and amending the General Civil Code, the Marriage Law, and the Rules of Jurisdiction. Date of entry into force: 1 July 1992. (*Bundesgesetzblatt für die Republik Österreich*, 4 June 1992, No. 105, pp. 1299-1304) **Austr. 93.1**

The following are among the principal provisions of this Law.

*Article 1. The Reproductive Medicine Law (Secs. 1-25).* Sec. 1 (Definitions) defines "medically assisted procreation" (referred to hereinafter as "MAP") to mean the application of medical methods in order to induce pregnancy by means other than sexual intercourse. The methods of MAP include, in particular: (1) the introduction of sperm into a woman's genital organs; (2) the union of oocytes and spermatozoa outside a woman's body; (3) the introduction of viable cells into a woman's uterus or fallopian tube; and (4) the introduction of oocytes or a combination of oocytes and sperm into a woman's uterus or fallopian tube. The term "viable cells" is defined to mean fertilized oocytes and cells that have developed from such oocytes.

Sec. 2 (Admissibility) lays down that MAP is admissible only within the context of marriage or a relationship that approximates to matrimony. Furthermore, it is admissible only if, taking into account the current state of science and experience, all other possible and reasonable treatments aimed at achieving pregnancy by means of sexual intercourse have proved unsuccessful or are doomed to failure. Sec. 3 lays down that, for the purposes of MAP, only the oocytes and sperm of married couples or couples living together on a permanent basis may be used. However, for the purposes of the method referred to in item (1) in Sec. 1, the sperm of a third person may be used if the husband's or partner's sperm is incapable of reproduction. Oocytes and viable cells may be used only in the woman from whom they have been obtained. Sec. 4 deals in detail with professional competence to undertake MAP (this may be undertaken only by a specialist in obstetrics or gynaecology who is authorized to engage in independent practice). Sec. 6 (Freedom to participate and prohibition of discrimination) reads as follows:

"6. (1) No physician shall be required to carry out or participate in MAP. This shall also apply in the case of persons practising within a specialized nursing service, a medico-technical service, or an ancillary health service.

(2) No person shall be subjected to any discrimination whatsoever if he carries out MAP in accordance with the provisions of this Law, if he participates in such MAP, or if he refuses to participate."

Under Sec. 7 (Counselling), the physician is required, before performing MAP, to provide detailed information and advice to the husband or partner concerning the method used and the possible consequences and risks that the treatment entails for the woman and for the desired child. The physician is to arrange psychological counselling or psychotherapeutic care for the husband or partner, provided that the latter has no objections thereto. In all cases involving an unmarried partner, and in cases involving a husband if a third person's sperm is to be used, MAP must be preceded by thorough counselling before a court or a notary concerning the legal consequences of consent, as referred to in Sec. 8. Detailed provisions concerning consent are laid down in Sec. 8. Secs. 9 and 10 are preceded by the heading

*International Digest of Health Legislation*, 1993, 44 (2)

“Utilization, examination, and treatment of sperm, oocytes, and viable cells” and read as follows:

“9. (1) Viable cells may not be used for any purpose other than MAP. They may be subjected to examination and treatment only if, taking into account the current state of medical science and experience, such action is necessary in order to achieve pregnancy. This shall also apply in the case of sperm or oocytes intended for use in MAP.

(2) Interventions involving the germline shall not be permitted.

(3) The use of a mixture of sperm from different males shall not be permitted for the purposes of MAP.

10. In the case of the union of oocytes with spermatozoa outside the woman’s body, only as many oocytes may be fertilized as is necessary, taking into account the current state of medical science and experience, within a single menstrual cycle for a promising and reasonable MAP.”

Secs. 11-16 deal in detail with the use of sperm from a third person (it is laid down in Sec. 16 that the provision of sperm for purposes of MAP may not result in any legal transaction involving remuneration). Sec. 17 (Storage) reads as follows:

“17. (1) Sperm and oocytes intended for use in MAP, as well as viable cells, may be stored for a period not exceeding one year.

The conditions of storage shall correspond to the current state of science and technology.

(2) Viable cells may not be transferred to the person from whom they were obtained, or to any other persons or establishments. The same provisions shall apply in the case of sperm and oocytes that are to be used, or could be used, for MAP.”

Detailed provisions are laid down in Secs. 18-19 on record-keeping, reporting, etc. Sec. 20 (Information) deals with access to information concerning third persons who provide sperm, and related matters. Sec. 21 imposes a ban on the use of intermediaries in order to obtain viable cells, sperm, and oocytes for the purposes of MAP, etc. Penal provisions are laid down in Secs. 22-25.

*Article II. Amendments to the General Civil Code.* The amendments to the Code deal with such matters as legitimacy, paternity, etc.

*Article III. Amendments to the Marriage Law.* Under the terms of an amendment to Sec. 48 of the Law of 1938 on the consolidation of the law on marriage and divorce, as amended, it is laid down that a marriage partner does not have grounds for divorce if the other partner refuses MAP.

*Other Articles.* Article IV deals with amendments to the Rules of Jurisdiction of 1895, as amended. Final and transitional provisions are laid down in Article V.

**DENMARK.** Law No. 503 of 24 June 1992 on the scientific ethics committee system and the examination of biomedical research projects. (*Lovtidende*, 1992, Part A, 26 June 1992, No. 84, pp. 2017-2020)

**Den. 92.32**

The following are among the principal provisions of this Law, which amends Law No. 353 of 3 June 1987 on the establishment of an Ethical Council and the regulation of certain forms of biomedical research (see *IDHL*, 1988, 39, 95, **Den. 88.1**), as amended by Law No. 315 of 16 May 1990.

Sec. 1 of Chapter 1 (The committee system) lays down that the purpose of this Law is to establish the legal framework for the scientific evaluation of biomedical research projects. The system is to have the task of ensuring: (1) the protection of persons participating in biomedical research projects; and (2) the development of new and valuable knowledge. Sec. 2 deals with the establishment (by the county councils) of regional committees, and Sec. 3 with the membership and working procedures thereof. Sec. 4 deals with the establishment (by the Minister of Education and Research) of the Central Scientific Ethics Committee, its membership, and working procedures. Sec. 5 lays down, *inter alia*, that the Central Committee is to cooperate closely with the Ethical Council.

Sec. 6 of Chapter 2 (Notification and authorization) reads as follows:

"6. All biomedical research projects involving experiments on the following shall be notified to the regional committee competent for the area in which the project leader carries out his activities:

1. living human beings [*levendefødte menneskelige individer*];
2. human gametes to be used for fertilization, fertilized human oocytes, embryos, and fetuses;
3. tissues, cells, and genetic material [*arvebestanddele*] from human beings, fetuses, and the like; and
4. deceased persons.

(2) The same shall apply to research projects in which biomedical research, as referred to in subsection 1, constitutes an important part of the project as a whole, and to the examination of questionnaires and files dealing with the fields concerned.

(3) The Central Committee may lay down rules for the practical organization of the scientific assessment of projects carried out by several research institutions (multi-centre research)."

Sec. 7 lays down, *inter alia*, that projects referred to in Sec. 6 may not be implemented until a scientific assessment has been made and the regional committee has given its authorization; the regional committee and the Central Committee may request that projects be amended, and may issue advice and guidance with regard to the formulation of projects. If the regional committee cannot reach agreement on a project, the matter is to be submitted to the Central Committee. The committees are to make use of consultants if they do not possess the necessary technical expertise to evaluate the projects submitted to them.

Sec. 8 of Chapter 3 (Tasks of the committee system) lays down, *inter alia*, the duties of the committees. In particular, they are to ensure that: any risks associated with the implementation of a project are carefully evaluated; patients or healthy research subjects are informed both orally and in writing of the content of the project and its foreseeable risks and advantages, their free and express consent being given in writing; information is provided to, and consent obtained from, the next-of-kin, guardian, or donor, as appropriate; it is clear from the information provided that the

*International Digest of Health Legislation*, 1992, 43 (4)

persons concerned may, at any time, withdraw their consent; and the project conforms to good scientific standards and adequate grounds exist for carrying it out. Sec. 9 lays down, *inter alia*, that the committee concerned is to ensure that projects are carried out in accordance with the authorization referred to in Sec. 7. Under Sec. 10, committees are to keep abreast of current developments in biomedical research, and are to endeavour to disseminate knowledge concerning the ethical issues connected therewith. Sec. 11 assigns the following tasks to the Central Committee: coordinating the work of the regional committees, laying down guidelines, and advising these committees on issues involving science and ethics; monitoring the development of research, and working towards the understanding of ethical problems that such development raises with regard to the public, the authorities, etc.; and examining research projects submitted to the committee. Under Sec. 12, a research worker may, if he has not received authorization from a regional committee, submit the matter to the Central Committee. Sec. 13 deals with the submission of annual reports on the activities of the regional and Central Committees.

Secs. 14 and 15 of Chapter 4 (Research on fertilized human oocytes and human gametes intended for fertilization) read as follows:

“14. Biomedical research on fertilized human oocytes and gametes intended for fertilization may, in accordance with the requirements laid down in Sections 6-8, only be carried out after authorization from both the regional and Central Committees, if the purpose of such research is to improve *in vitro* fertilization in order to bring about pregnancy. The same shall apply to other treatments for involuntary sterility, in which a woman's oocytes are fertilized outside the uterus.

(2) The removal and fertilization of oocytes with a view to carrying out experiments other than those referred to in subsection 1, shall not be permitted.

(3) Fertilized oocytes may only be kept alive outside a woman's uterus 14 days from the time of fertilization, not including the period during which the fertilized oocytes were frozen.

(4) Fertilized human oocytes that have been used in biomedical research, in accordance with subsection 1, may not be introduced into a woman's uterus, unless this can be done without any risk of transmitting hereditary diseases, defects, deformities, or the like.

(5) The donation of fertilized human oocytes shall not be permitted.

(6) The Minister of Health shall be empowered to issue regulations on the freezing and donation of human oocytes.

15. The following experiments shall be prohibited:

1. experiments whose purpose is to enable the production of genetically identical human beings;
2. experiments whose purpose is to enable the production of human beings by the fusion of genetically different embryos or parts of embryos prior to their implantation in the uterus;
3. experiments whose purpose is to enable the production of living human beings who are hybrids with a genetic constitution including components from other species; and
4. experiments whose purpose is to enable the development of human beings in the uterus of another species.”

The other Chapters are the following: 5. Financing (Sec. 16); 6. Penal provisions (Sec. 17); and 7. Entry into force, etc. (Secs. 18-20).

**DENMARK.** Order No. 650 of 22 July 1992 on the freezing and donation of human oocytes. (*Lovtidende*, 1992, Part A, 31 July 1992, No. 103, pp. 2721-2722) **Den. 92.33**

This Order has been made by the Ministry of Health in pursuance of subsection 6 of Sec. 14 of Law No. 503 of 24 June 1992 on the scientific ethics committee system and the examination of biomedical research projects (see p. 758, **Den. 92.32**).  
Secs. 1-11 read as follows:

*"Freezing of unfertilized human oocytes"*

1. (1) Unfertilized human oocytes may be frozen with a view to:

1. subsequently returning the oocyte to the woman who provided it;
2. donation for research purposes; and
3. donation for the purpose of impregnating another woman.

(2) Before freezing takes place, the woman concerned shall give her written consent to freezing and storage. She shall be informed in advance, both orally and in writing, of the consequences of freezing.

(3) The woman concerned shall, at the same time, declare that she agrees to the conditions and requirements governing freezing, as laid down in this Order.

2. (1) Unfertilized human oocytes may not be frozen for more than one year. At the end of this year, they shall be destroyed. Oocytes that have been frozen with a view to returning them to the woman who provided them shall also be destroyed, if the woman dies within one year of the date of freezing.

(2) Unfertilized human oocytes that have been frozen with a view to returning them to the woman who provided them may only be unfrozen and used in accordance with the woman's wishes. Requests to unfreeze human oocytes may only be made with regard to treatment on medical grounds (see, however, items 2 and 3 of subsection 1 of Section 1, on donation).

*Freezing of fertilized human oocytes*

3. (1) Fertilized human oocytes may be frozen with a view to:

1. subsequently returning the fertilized oocyte to the woman from whom it originates; or
2. research, in accordance with subsection 1 of Section 14 of the Law on the scientific ethics committee system and the examination of biomedical research projects.

(2) Before freezing takes place, the couple concerned shall give their written consent to freezing and storage. They shall be informed in advance, both orally and in writing, of the consequences of freezing.

(3) The couple concerned shall, at the same time, declare that they agree to the conditions and requirements governing freezing, as laid down in this Order.

4. (1) Fertilized human oocytes may not be frozen for more than one year. At the end of the year, they shall be destroyed. Oocytes shall also be destroyed in the event of the death of one of the parties, or their separation or divorce, within one year of the date of freezing.

(2) Fertilized human oocytes may only be defrozen and used if the couple concerned gives their written consent to each treatment cycle.

*Donation with a view to achieving pregnancy*

5. The donation of fertilized human oocytes shall not be permitted (see subsection 5 of Section 14 of the Law on the scientific ethics committee system and the examination of biomedical research projects).

6. The donation of unfertilized human oocytes shall be permitted.

7. Unfertilized human oocytes may be donated with a view to:

1. impregnating another woman; or
2. research.

8. The removal of unfertilized human oocytes for the purpose of donation in order to impregnate another woman may only be permitted in connection with IVF treatment or comparable procedures.

9. (1) The donor shall give written consent to the donation. She shall be informed beforehand of the consequences of donation.

(2) The donor shall, at the same time, declare that she agrees to the conditions and requirements laid down in this Order with regard to donation. Finally, the donor shall be guaranteed a reasonable period of time for consideration.

10. The donor may withdraw her consent to donation, up until the time that fertilization of the human oocyte may take place.

11. The donor shall be guaranteed anonymity. A donor may not obtain information concerning the identity of the couple or child concerned."



No. 67

**SENATE**

FIRST REGULAR SESSION OF 1992-1993

APPENDIX TO MINUTES OF THE SESSION OF NOVEMBER 26, 1992.

**BILL**

ADOPTED BY THE NATIONAL ASSEMBLY.

regarding the donation and utilisation of parts and products of the human body, to medically assisted procreation, and to prenatal diagnostics, as well as to the National Consultative Commission on Ethics for Life Sciences and Health.

TRANSMITTED BY

THE PRIME MINISTER

TO

THE PRESIDENT OF THE SENATE

(Referred to the Committee on Social Affairs, subject to possible convening of a special commission under the conditions envisioned by the regulations.)

The National Assembly has adopted on first reading a bill, the content of which follows:

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**See numbers:**

**National Assembly (9th legisl.): 2600, 2871, and T.A. 735.**

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**Life, medicine, and biology**

Article I A (new).

The National Consultative Commission on Ethics for Life Sciences and Medicine has the mission of giving its advice on the ethical problems that are raised by research and practice in the fields of biology, medicine, and health and of publishing its recommendations on these subjects.

Matters can be referred to the Commission by the President of the National Assembly, the President of the Senate, the Prime Minister, a public institution or a recognized foundation of public utility having as its principal activity technological research and development, or an institution of higher education. It can also take jurisdiction over any question relevant to its competence and publish its recommendations.

The Commission is notified about bills involving questions raised by research in the fields of biology, medicine, and health.

The Commission participates in informing the public and interested participants about questions relevant to its competence and their foreseeable developments. It likewise participates in the development of instruction about biomedical ethics.

The Commission submits to the President of the Republic and to Parliament an annual report in which it presents the results of its activities. This report is published.

The funds necessary for the Commission to accomplish its mission are included in the Prime Minister's general services budget. The provisions of the law of August 10, 1922, relating to financial controls are not applicable to management of the funds. The accounts are presented to the Revenue Court for auditing.

The president of the Commission is nominated by decree of the President of the Republic.

In addition to its president, the Commission is composed of:

- persons designated by the President of the Republic and belonging to the principal philosophical and spiritual families;

- qualified persons chosen by reason of their competence and their interest in problems of ethics, including one member of the National Assembly and one member of the Senate appointed by the presidents of the these assemblies;

- persons belonging to the research sector.

The list of members is published in a joint order of the Keeper of the Seals, the minister responsible for health, and the

minister responsible for research.

The composition and methods of organization and operation of the Commission are specified by decree.

#### Article I.

The heading of Book VI of the Public Health Code is revised as follows:

"Book VI. -- Donation and utilization of parts and products of the human body, medically assisted procreation, and prenatal diagnostics."

#### Art. II.

There will be inserted into Book VI of the Public Health Code a Title I, entitled as follows:

#### "TITLE I.

#### "PRINCIPLES AND RULES APPLICABLE TO THE DONATION AND UTILIZATION OF PARTS AND PRODUCTS OF THE HUMAN BODY."

#### Art. III.

Chapter I of Title I of Book VI of the Public Health Code is revised as follows:

#### "CHAPTER ONE.

#### "General principles.

"Art. L. 666-1. -- Transfer and utilization of parts and products of the human body are regulated by the provisions of Chapter II of Title I of Book I of the Civil Code and by the provisions of the present chapter.

"Art. L. 666-2. -- Removal of parts and collection of products of the human body cannot be performed without the consent of the donor. This consent is revokable at any time.

"Art. L. 666-3. -- Publicity on behalf of donation or parts or products of the human body for the benefit of a particular person or a particular institution or organization is prohibited. This prohibition does not constitute an obstacle to publicity on behalf of donation of parts and products of the human body.

"Publicity on behalf of the donation of parts and products of the human body is done under the responsibility of the

Ministry of Health and according to methods established by decree of the Council of State.

"Art. L. 666-4. -- No financial remuneration can be granted to anyone who submits to the removal of parts or the collection of products of his body, with the exception, if the case arises, of reimbursement of expenses incurred, in ways established by decree.

"Art. L. 666-5. -- The donor may not know the identity of the recipient, nor the recipient that of the donor. No information that permits identification at the time of who has made the donation of a part or a product of his body and the one who has received it can be divulged.

"This principle of anonymity cannot be violated except in case of therapeutic necessity.

"Art. L. 666-6. -- Parts and products of the human body cannot be used for therapeutic purposes unless the donor has undergone screening tests for infectious diseases under conditions established by decree.

"Art. L. 666-7. -- Products of the human body for which it is not customary to apply the principles stated in articles L. 666-2 through L. 666-6 are not subject to the provisions of the present chapter. The list of these products is established by decree of the Council of State."

#### Art. IV.

Chapter II of title one of Book VI of the Public Health Code is revised as follows:

#### "CHAPTER II.

##### "Organs.

##### "Section 1.

##### "General provisions.

"Art. L. 667-1. -- Bone marrow is considered as an organ for application of the provisions of the present book.

"Art. L. 667-2. -- Regulatory measures determine, if necessary, the methods of application of the present chapter. Unless otherwise provided, they are covered by decrees of the Council of State.

##### "Section 2.

"Art. L. 667-3. -- Organ removal from a living person for

the purpose of donation cannot be performed except in the direct therapeutic interest of the recipient. The recipient should have the relationship of father or mother, son or daughter, or sister or brother of the recipient, except in the case of removal of bone marrow for the purpose of grafting.

"In case of emergency, the donor can be the spouse.

"The donor, having been previously informed of the risks incurred by and possible consequences of the removal, should express his consent to the president of the departmental court or a magistrate appointed by him. In case of emergency, the consent is obtained by whatever means by the public prosecutor. This consent is revokable without formality at any time.

"Art. L. 667-4. -- No organ removal can take place for the purpose of donation from a living minor or from a living adult who is the subject of a legal protection measure.

"Art. L. 667-5. -- In spite of the provisions of article L. 667-4, removal of bone marrow may be performed on a minor for the benefit of his brother or sister.

"This removal can only be performed after authorization by a committee of experts and subject to the consent of each of those authorized to exercise parental authority or of the legal representative of the minor. The consent is expressed to the president of the departmental court or the magistrate designated by him, who may hear from the minor if he considers it appropriate.

"In case of emergency, the consent is obtained by any means whatever by the public prosecutor.

"The committee assures itself that the minor has been informed of the envisaged removal, with the purpose of permitting him to express his will, if he is capable of doing so.

"Refusal by the minor constitutes an obstacle to the removal.

"Art. L. 667-6. -- The committee of experts mentioned above is composed of three members appointed for three years by an order of the minister in charge of health. It consists of two physicians, one of whom is a pediatrician, and one person who does not belong to the medical professions.

"The committee states its opinion in regard to the general principles and regulations stated in the present title. It evaluates the medical justification for the operation, the risks that it may entail, as well as the foreseeable consequences on the physical and psychological levels.

"Section 3.

"Organ removal from a deceased person.

"Art. L. 667-7. -- Organ removal from a deceased person can only be performed for therapeutic or scientific purposes and after a state of death has been established under conditions defined by decree of the Council of State.

"Any person may make known in his lifetime his refusal of or consent to organ removal after his death, by any means, especially by indicating his will to an automated national registry envisioned for this purpose, on his social-security card, or on a specific card. This is revokable at any time. The conditions of operation and management of this registry are determined by decree of the Council of State.

"If the physician does not have direct knowledge of the will of the deceased, he should make efforts to obtain the testimony of the family or next of kin of the deceased concerning his will.

"No removal can be performed if the will of the deceased, expressed directly or by the testimony of his family or next of kin, is opposed to it.

"Art. 667-8. -- If the deceased person was a minor or an adult who is the subject of a legal protection measure, removal for the purpose of donation can only take place on condition that each of those authorized to exercise parental authority or of the legal representative gives express written consent for it.

"Art. 667-8a (new). -- No removal for scientific purposes, other than those having the purpose of investigating the causes of the death, can be performed without the consent of the deceased, expressed directly or through testimony of his family.

"Art. L. 667-9. -- The physicians who establish the state of death and those who perform the removal or transplantation should belong to separate medical units.

"Art. L. 667-10. -- Physicians who have performed a removal from a deceased person are obligated to assure decent restoration of his body.

"Section 4.

"Authorization of institutions performing organ removals for the purpose of donation.

"Art. L. 667-11. -- Organ removals can only be performed in health institutions authorized for this purpose by administrative authority.

"Authorization is granted for a period of five years. It is renewable.

"Art. L. 667-12. -- No remuneration for services can be

received by those performing organ removals for this activity.

"Art. L. 667-13. -- The technical, health, and medical conditions and the conditions appropriate to guarantee operation in conformity with the general principles stated in the present title, which public and private institutions of health participating in the public hospital service should fulfill in order to be authorized to perform organ removals are determined by decree of the Council of State.

"Section 5.

"Organ transplants.

"Art. L. 667-13a (new). -- The provisions of article L. 668-10 are applicable to organs when they can be preserved. The list of these organs is established by decree.

"For application of these provisions to organs, granting of the authorization mentioned in art. L. 668-10 is subject to the conditions envisioned in article L. 668-13.

"Art. L. 667-14. -- Persons for whom an indication for organ transplant has been given are inscribed on a national list.

"The methods for establishing and managing this list and the criteria for allocation and assignment of organs are determined by decree of the Council of State.

"Art. L. 667-15. -- Organ transplants are preformed in health institutions authorized for this purpose under the conditions envisioned by the provisions of sections 1 and 2 of chapter II of title I of book VII of the present code, with the exclusion of the third paragraph of article L. 712-16.

"Authorization to perform organ transplants may be received by institutions authorized to preform organ removals in application of article L. 667-11 and which, in addition, give assurance of medical-teaching and medical-research activities under the conditions envisioned by the provisions of ordinance no. 58-1373 of December 30, 158, relating to the creation of hospitals and university centers, to the reform of medical instruction and to the development of medical research, but equally to health institutions connected by contract to the preceding within the framework of the public hospital service.

"Art. L. 667-16. -- No remuneration for services can be received by those who perform organ transplants for these activities."

Art. V.

Chapter III of title I of book VI of the Public Health Code is

revised as follows:

"CHAPTER III

"Tissues, cells, and products

"Section 1.

"General provisions.

"Art. L. 668-1. -- The present book is not applicable to tissues, cells, and products detached from the human body within the framework of a diagnostic or therapeutic procedure and which do not constitute the object of a donation.

"The provisions of sections 2 and 3 of the present chapter do not apply to tissues and products detached from the human body either for the purpose of a diagnostic procedure or within the framework of a therapeutic procedure that does not have the purpose of tissue removal or of collecting a product envisioned for donation.

"Art. L. 668-2. -- The provisions of sections 2 and 3 of the present chapter are applied subject to the provisions of book IIA relating to the protection of persons who present themselves for biomedical research.

"Art. L. 668-3. -- Regulatory measures determine, if necessary, the methods of application of the present chapter. Unless otherwise provided, they are covered by decrees of the Council of State.

"Section 2.

"Removal of tissues and cells and collection of products of the human body for the purpose of donation.

"Art. L. 668-4. -- Removal of tissues or cells or collection of products of the human body from a living person can only be performed for a therapeutic or scientific purpose.

"Art. L. 668-5. -- No removal of tissue or cells, no collection of products of the human body can take place from a living minor or from a living person who is the subject of a legal protection measure.

"Art. L. 668-6. -- Removal of tissue or collection of products of the human body from the deceased person can only be performed for therapeutic purposes, under the conditions envisioned in section 3 of chapter II of the present title.

"Section 3.

"Authorization of institutions and organizations



performing tissue or cell removal from the human body  
for the purpose of donation.

"Art. L. 668-7. -- Tissue removals can only be performed in health establishments authorized for this purpose by administrative authority.

"Authorization is granted for a period of five years. It is renewable.

"Art. L. 668-8. -- No remuneration for services can be received by those performing tissue removals for this activity.

"Art. L. 668-9. -- The technical, health, and medical conditions and the conditions appropriate to guarantee operation in conformity with the general principles stated in the present title, which public and private institutions of health participating in the public hospital service should fulfill in order to be authorized to perform organ removals are determined by decree of the Council of State.

"Section 4.

"Preservation and utilization of tissues and cells  
of the human body.

"Art. L. 668-10. -- Only public health institutions and non-profit organizations authorized for this purpose by administrative authority can provide transformation, preservation, distributions, transfer, import, and export of tissues and cells.

"By exception, and for a period not to exceed five years, authorization to perform transformation of removals or establishment of cell cultures can be granted to other organizations for activities that cannot be performed under equivalent conditions by the institutions and organizations mentioned in the above paragraph.

"Art. L. 668-11. -- Transformation, distribution, and transfer of tissues and cells, are, if necessary, subject to regulations, especially financial and economic, appropriate to assure respect for the provisions of the present title and are established by decree of the Council of State.

"Art. L. 668-11a (new). -- Grafts of tissues and cells can only be done in health institutions.

"Activities requiring high technology or necessitating particular provisions in the interest of public health, determined by decree of the Council of State under conditions envisioned by sections 1 and 2 of chapter II of title I of book VII of the present code can only be performed in institutions of health authorized for this purpose.

"Art. L. 668-13. -- Granting of the authorizations mentioned in articles L. 668-10 and L. 668-12 is subject to technical, health, or medical conditions, and, if necessary, financial, as well as to conditions appropriate to guarantee operation in conformity with the general principles state in the present title.

"Conditions are methods for granting of each of these authorizations are established by decree of the Council of State.

#### Art. Va (new).

Chapter IV of title I of the book VI of the Public Health Code is revised as follows:

#### "CHAPTER IV

##### "The monitoring commission.

"Art. L. 669-1. -- A monitoring commission responsible for participating in evaluation and monitoring of activities of removal and transplantation of grafts of organs, tissues, and cells of human origin, with the exception of blood and gametes.

"The commission formulates all observations and suggestions it considers useful and submits an annual report.

"It is consulted on all questions relating to activities defined in the first paragraph, especially on the drafts of the decrees mentioned in articles L. 667-7, L. 667-13, L. 667-13a, L. 667-14, L. 668-3, L. 668-9, L. 668-11, and L. 668-13.

"An order of the Ministry of Health establishes the composition of the commission and the methods of its organization and its operation.

"Art. L. 669-2. -- The ministry responsible for health communicates to the monitoring commission all documents useful for the needs of its mission.

"Art. L. 669-3. -- The members of the monitoring commission and the persons named to collaborate in its work are obligated, under the conditions and penalties envisioned in article 378 of the Penal Code, to keep secret the information it may knowledge of by reason of its operations."

#### Art. VI.

I. -- The single chapter of book VI of the Public Health Code becomes chapter V of title I, entitled: "Therapeutic utilization of human blood, its plasma, and their derivatives."

II. -- Articles L. 666, L. 667, L. 668, L. 669, L. 670, L. 671, L. 672, L. 673, L. 674, L. 675, L. 675-1, L. 676, and L. 677 of the Public Health Code become respectively articles L. 670-1, L. 670-2, L. 670-3, L. 670-4, L. 670-5, L. 670-6, L. 670-7, L. 670-8, L. 670-9, L. 670-10, L. 670-11, L. 670-12, and L. 670-13 of the same code.

#### Art. VII

There is inserted into book VI of the Public Health Code a title II, entitled:

## TITLE II

### MEDICALLY ASSISTED PROCREATION

#### Art. 8

The first chapter of Title II of Book VI of the public health code is hereby written:

#### FIRST CHAPTER

#### Common Provisions

Art. L. 671-1. - Medically assisted procreation means medical and biological techniques permitting procreation beyond natural processes.

Art. L. 671-2. - Medically assisted procreation is designed to respond to the parental project of a couple. Its exclusive purpose is to allay an infertility of a pathological character that has been medically determined or to prevent the transmission of a particularly serious and incurable disease to the child.

The man and the woman forming the couple, at an age of procreating, must be alive and consensual at the time of insemination or implantation of the embryos.

Art. L. 671-2 bis (new). - No embryo can be conceived *in vitro* outside of the parental project.

At the request of both partners of the couple, the embryos that were not transferred can be conserved in view of the future pursuit of their parental project.

The duration of the conservation cannot exceed five years, unless the couple wishes to pursue its parental project beyond such duration.

Both partners of the couple must be consulted on the point of knowing whether they maintain their conservation request. Their decision must be expressed in writing.

The conservation of the embryos can be stopped at any time upon the written request of one of the two partners of the couple. The two partners of the couple can also consent in writing that the conserved embryos be used in the parental project of another couple under the conditions provided in Article L. 672-6.

In addition, the two partners of the couple can specify that they accept, when the conservation is stopped, and as a special circumstance, that scientific research can be effected under the conditions provided in Article L. 672.7.

The establishments authorized to practice the activities of medically assisted procreation must include in the annual report of activity provided under Article L. 673-4 all information relative to the development of the embryos which were subject to conservation.

However, the embryos existing at the date of promulgation of Law No. - dated and for which it has been verified that they are no longer under a parental

project must be proposed for a transfer to a couple fulfilling the conditions provided under Article L. 672-6 in view of implementing a parental project after notification of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics, in accordance with the methods defined by a decree in the Conseil d'Etat. The conservation is stopped after arriving at a period of five years.

Art. L. 671-2 *ter* (new). - Commercial and industrial use of embryos is prohibited.

Art. L. 671-3. - Clinical and biological acts of medically assisted procreation, defined by decree in the Conseil d'Etat, are performed under the responsibility of a practitioner specifically approved for such purpose in each establishment or laboratory authorized to practice them.

Art. L. 671-3 *bis* (new). - As soon as the physician is consulted in view of an act of medically assisted procreation, he must, during a private interview:

1. verify the motivation of both partners of the couple and recall the possibilities open by law in matters of adoption;
2. inform them of the probabilities of success and failure of the techniques of medically assisted procreation as well as their possible painfulness;
3. provide them with a guide-dossier, brought up to date at least once a year, comprising particularly:
  - a) the recall of the legislative and regulatory provisions relative to medically assisted procreation;
  - b) a description of these techniques;
  - c) the recall of the legislative and regulatory provisions relative to adoption, together with the address of the associations and organizations which might provide additional information on this subject.

A decree details under which conditions the governmental agencies of health and social affairs ensure the implementation and distribution of the guide-dossiers to be furnished to physicians.

At the end of a one-month period of reflection both partners of the couple are authorized to confirm in writing their request to the physician.

A medical interview must be systematically proposed to the couple in the case where the latter modifies its parental project or renounces it under the conditions provided in Article L. 671-2 *bis*.

## Art. 9

Chapter II of Title II of Book VI of the public health code is hereby written:

### CHAPTER II

#### *Medically Assisted Procreation With Third-Party Donor*

Art. L. 672-1. - The donation of gametes consists of providing one third of sperm or oocytes in view of the objectives enunciated in Article L. 671-2.

Art. L. 672-2. - The donation of gametes is subject to the provisions of Articles L. 666-2 to L. 666-6 without prejudice to the provisions of the present chapter.

Art. L. 672-3. - The donor's consent is compiled in writing.

The same applies to the consent of both partners of the receiving couple, which can be revoked, prior to any intervention, by either partner of the couple.

Art. L. 672-4. - The number of children born from a medically assisted procreation with the gametes of a same donor cannot exceed a limit fixed by decree of the minister in charge of health.

Art. L. 672-5. - Any insemination by fresh sperm derived from a donation is prohibited.

Art. L. 672-6. - The transfer to another couple of an embryo resulting from *in vitro* fecundation is subject to the provisions of Articles L. 666-2 to L. 666-6. Such transfer can be accomplished only when each partner of the receiving couple shows a sterility of a pathological character that has been medically determined or a particularly serious and incurable disease. It is subordinated to the written consent of both partners of the donating and receiving couples.

Art. L. 672-7 (new). - Research projects on the human embryo are submitted to prior opinion of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics, in accordance with the methods defined by a decree in the Conseil d'Etat. Each year this commission renders public the list of establishments performing research on the embryo together with the purpose of the research.

#### Art. 10

Chapter III of Title II of Book VI of the public health code is hereby written:

### CHAPTER III

#### *Authorization of Medically Assisted Procreation Activities*

Art. L. 673-1. - The clinical activities of medically assisted procreation, with the exception of artificial insemination, can be practiced only in health establishments and medical analysis laboratories authorized according to the conditions provided by the present law.

However, the activities involved in gathering, treatment, conservation and transfer of gametes in view of donations as well as the activities involved in conservation and transfer of embryos intended to implement the parental project of another couple can be practiced only in public and private non-profit health establishments. No remuneration for the act can be received by practitioners as a result of these activities.

With the exception of artificial insemination, the activities of medically assisted procreation, both clinical and biological, as well as the transfer of gametes, must be authorized in accordance with the procedures stipulated by the provisions of Sections 1 and 2 of Chapter II of the First Title of Book VII, to the exclusion of the third paragraph of Article L. 712-16. This authorization is tantamount to derogation, within

the meaning of the provisions of the sixth paragraph of Article L. 761, for medical analysis laboratories.

In order to be authorized to exercise these activities, the establishments and laboratories mentioned in the first and second paragraphs of the present article must fulfill the conditions determined in application of the abovementioned provisions of Book VII and the conditions defined by decree of the Conseil d'Etat, suitable to guarantee a commitment conforming to the general principles provided by the present title.

The authorization covers one or several medically assisted procreation activities, with or without third-party donor. It is issued for a duration of five years. It is accorded after opinion of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics, instituted by Article L. 673-3. This opinion is obtained prior to that of the National Committee of Health and Social Organization.

Art. L. 673-2. - Any establishment or laboratory authorized to practice medically assisted procreation activities or prenatal diagnostics, any multidisciplinary center of prenatal diagnostics must present to the minister in charge of health, an annual report of activities according to the procedures determined by such minister's decree.

Art. L. 673-3. - The National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics is in charge of giving an opinion on the requests for authorization to exercise medically assisted procreation activities and prenatal diagnostics as well as approval requests from multidisciplinary centers of prenatal diagnostics. It participates in the follow-up and evaluation of the operation of the authorized establishments and laboratories.

Each year it submits to the minister in charge of health a report covering the evolution of the medicine and biology of reproduction and prenatal diagnostics.

The National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics includes practitioners designated by proposals of their representative organizations; personalities selected by reason of their competence in the fields of procreation, prenatal diagnostics, genetic counseling and the right of filiation; and representatives of the involved governmental agencies as well as a representative of family associations.

The commission designates its president among its members.

A decree by the Conseil d'Etat establishes the composition of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics and determines the procedures for its organization and operation.

Art. L. 673-4. - The minister in charge of health transmits to the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics, the report mentioned in Article L. 673-2 and all appropriate documents for the requirements of its mission.

Art. L. 673-5. - The members of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics and the persons called upon to collaborate in its work are required, in the conditions and under the penalties provided in Article 378 of the penal code, to keep secret the information that they may have learned by reason of their functions.

Art. 10 bis (new)

A Title II bis written as follows is inserted into Book VI of the public health code:

TITLE II BIS

PRENATAL DIAGNOSTICS

Art. 1. 673-6. - The purpose of prenatal diagnostics is a diagnostic or therapeutic intervention on the embryo or the fetus. Its goal can only be to anticipate or to treat an ailment of a particular gravity, in the interest of the child to be born.

Genetic counseling as well as analyses of molecular and chromosomal genetics in view of establishing a prenatal diagnostic can be practiced only in health establishments and in medical biology analysis laboratories authorized according to the conditions defined in Articles L. 673-1 and L. 673-2. The conditions for creating and approving, and the missions of multidisciplinary prenatal diagnostics centers are defined by decree of the Conseil d'Etat.

When any prenatal diagnostic leads to envision a voluntary interruption of pregnancy for a therapeutic motive, it must be confirmed by two authorized physicians, one of which must exercise his activity in a multidisciplinary prenatal diagnostics center mentioned in the preceding paragraph.

Registers shall be established and kept by the multidisciplinary prenatal diagnostics centers, and shall indicate the causes of the therapeutic pregnancy interruption and shall permit verifying the authenticity of the anomaly detected by the prenatal diagnostic.

Art. 11

A Title III entitled as follows is inserted into Book VI of the public health code:

TITLE III

PENAL AND ADMINISTRATIVE SANCTIONS

Art. 12

The first chapter of Title III of Book VI of the public health code is hereby written:



## **FIRST CHAPTER**

### **Sanctions Relative to the Utilization of Organs, Tissues and Products of the Human Body**

**Art. L. 681-1.** - Any violation noted in the establishment or organization and hence of the legislative and regulatory requirements relative to the taking and the transplantation of organs; to the taking, conservation and utilization of tissues; or to grafts of tissues or cells of the human body; leads to the temporary or definitive revocation of the authorizations provided in Articles L. 667-11, L. 667-15, L. 668-7, L. 668-10 and L. 668-12.

The revocation of the authorization is also incurred in case of violation of the requirements fixed by the authorization.

The revocation is invoked only after a one-month period following a notification addressed by the administrative authority to the establishment or organization concerned, detailing the grievances. In case of emergency affecting the safety of the persons involved in the activities under question, a provisional suspension can be pronounced as a conservative measure.

The revocation decision is published in the "Journal Officiel" of the French Republic.

**Art. L. 681-2.** - The act of obtaining or of attempting to obtain from a person one of its organs for a payment, whatever the form, is punished by an imprisonment of six months to five years and a fine of 50,000 FF to 1 million FF.

Punishable with the same penalties is the act of bringing or attempting to bring intermediary action to favor the obtaining of an organ against the payment of the latter, or to cede subject to payment such an organ from the body of another.

The same penalties are applicable in the case where the organ obtained in the conditions provided in the first paragraph originate from a foreign country.

**Art. L. 681-3.** - The act of taking or attempting to take an organ on a living person without the consent of the latter having been obtained in the conditions provided in Article L. 667-3 is punished by an imprisonment of six months to seven years and a fine of 50,000 FF to 1 million FF.

Punishable with the same penalties is the act of taking or attempting to take, in violation of the provisions of Articles L. 667-4 and L. 667-5, an organ either on a live minor donor or on a live major donor subject to a measure of legal protection.

**Art. L. 681-4.** - The act of obtaining or of attempting to obtain from a person either the taking of one of his tissues or taking his blood or products of his body for a payment, whatever the form, is punished by an imprisonment of six months to five years and a fine of 50,000 FF to 1 million FF.

Punishable with the same penalties is the act of bringing or attempting to bring intermediary action to favor the obtaining of either tissues or human products or blood against the payment, whatever the form, or to cede subject to payment tissues, products or blood from the body of another.

**Art. L. 681-5.** - The act of taking or attempting to take either a tissue, or to take or to attempt to take a product or blood on a living person without the person

expressing consent is punished by an imprisonment of six months to five years and a fine of 50,000 FF to 1 million FF.

Punishable with the same penalties is the act of taking a tissue or taking, in violation of the provisions of Articles L. 668-5, a product on a live minor person or on a live major person subject to a measure of legal protection.

Art. L. 681-6. - The act of proceeding with the taking and the transplantation of organs; the taking or grafts of tissues; the conservation or the transformation of tissues; or the graft of cells in an establishment not having obtained the authorizations provided in Articles L. 667-11, L. 667-15, L. 668-7, L. 668-10 and L. 668-12, or in violation of the authorization regulations is punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

Art. L. 681-6. - The act of proceeding with the taking and the transplantation of organs; the taking or grafts of tissues; the conservation or the transformation of tissues; or the graft of cells in an establishment not having obtained the authorizations provided in Articles L. 667-11, L. 667-15, L. 668-7, L. 668-10 and L. 668-12, or in violation of the authorization regulations is punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

Art. L. 681-7. - The act of proceeding with the distribution or the transfer of parts and products of the human body or blood in view of a donation without the donor having been submitted to the tests for detecting transmissible diseases required in application of the provisions of Article L. 666.6 is punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

Art. L. 681-8. - The persons found guilty of one of the offenses provided in the present chapter are also liable to a complementary penalty of prohibition, for a duration of not more than ten years, to practice the professional or social activity in the exercise of which or at the occasion of which the infraction was committed.

#### Art. 13

Chapter II of Title III of Book VI of the public health code is hereby written:

#### *CHAPTER II*

#### *Sanctions Relative to Medically Assisted Procreation and Prenatal Diagnostics*

Art. L. 682-1. - Any violation noted in the establishment or the laboratory and hence of the legislative and regulatory requirements applicable to medically assisted procreation or to prenatal diagnostics leads to the temporary or definitive revocation of the authorizations provided in Articles L. 673-1 and L. 673-6.

The revocation of the authorization is also incurred in case of violation of the requirements fixed by the authorization.

The revocation is invoked only after a one-month period following a notification addressed by the administrative authority to the establishment or organization concerned, detailing the grievances. In case of emergency affecting the safety of the persons involved in the activities under question, a provisional suspension can be pronounced as a conservative measure.

The revocation decision is taken after motivated opinion of the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics. It is published in the "Journal Officiel" of the French Republic.

**Art. L. 682-2.** - The act of collecting or taking, or attempting to collect or take gametes on a living person without his written consent is punished by an imprisonment of six months to five years and a fine of 50,000 FF to 1 million FF.

Punishable with the same penalties is the act of obtaining or attempting to obtain human embryos without the written consent of both partners of the donating and receiving couples.

**Art. L. 682-3.** - Anyone who will have obtained or attempted to obtain gametes or human embryos for a payment, whatever the form, shall be punished by an imprisonment of six months to five years and a fine of 50,000 FF to 1 million FF.

Anyone who will bring or attempt to bring intermediary action to favor the obtaining of gametes or human embryos for a payment, whatever the form, or to release to others, subject to payment, gametes or human embryos derived from donations shall be punished with the same penalties.

**Art. L. 682-4.** - The act of divulging information permitting to identify both the person or the couple who donated gametes or embryos and the couple who received them is punished by an imprisonment of two months to two years and a fine of 5,000 FF to 50,000 FF.

**Art. L. 682-5.** - The act of collecting or taking gametes on a living person in view of medically assisted procreation without proceeding with the tests for detecting transmissible and genetic diseases required in application of the provisions of Article L. 656.6 shall be punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

**Art. L. 682-6.** - Whoever proceeds with medically assisted procreation activities for purposes other than those defined in Article L. 671.2 shall be punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

**Art. L. 682-7.** - Whoever proceeds with an insemination using fresh sperm derived from a donation in violation of the provisions of Article L. 672-5 shall be punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

**Art. L. 682-7 bis (new).** - Whoever proceeds with an interruption of pregnancy after prenatal diagnostic without having conformed to the procedures provided by the law shall be punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

**Art. L. 682-8.** - Whoever proceeds with activities involving medically assisted procreation or prenatal diagnostics without having obtained the authorizations provided in Article L. 673-1 and L. 673-6 or in violation of the requirements stipulated by such authorization shall be punished by an imprisonment of two months to two years and a fine of 5,000 FF to 500,000 FF.

**Art. L. 682-9.** - The persons found guilty of one of the offenses provided in the present chapter are also liable to a complementary penalty of prohibition, for a duration of not more than ten years, to practice the professional or social activity in the exercise of which or at the occasion of which the infraction was committed.

Art. 14

The establishments, laboratories or organizations which, in application of legislative and regulatory provisions in force prior to the effective date of the present law, have been authorized to practice the activities involved in taking organs, transplantation of organs and medically assisted procreation provided in Articles L. 667-11, L. 667-13, L. 673-1 and L. 673-6 of the public health code must submit an authorization request within a period of six months from the time of publication of the decree taken for the application of the present law and relative to the authorization concerning their activities. They can pursue their activities until the intervention of the administrative authority on their request.

The establishments, laboratories or organizations which practice the activities involved in the taking of tissues, the conservation or the transformation of tissues in view of their transfer, or grafts of tissues or cells that Articles L. 668-7, L. 668-10, and L. 668-12 of the public health code require authorization, must submit an authorization request within a period of six months from the time of publication of the decree taken for the application of the present law and relative to the authorization concerning their activities. They can pursue their activities until the intervention of the administrative authority on their request.

Art. 15

The following provisions are abrogated:

1. Law No. 49-980 of 7 July 1949 permitting the practice of cornea grafts with the aid of voluntary donors of eyes;
2. Law No. 76-1181 of 22 December 1976 relative to taking organs;
3. Article 13 of Law No. 91-1406 of 31 December 1991 covering various provisions of social order.

The provisions of the present article do not bar the application to the National Institute of Statistics and Economical Studies or to the ministerial statistics services of the provisions of Chapter V bis of Law No. 78-17 of 6 January 1978 relative to information processing, files and liberties.

*Deliberated in public session, at Paris, 25 November 1992.*

*The President,*  
**Signed: HENRI EMMANUELLI**

Art. 16 (new)

After evaluation of its application, the present law will be the subject of a new examination by the Parliament within a period of five years after its effective date and not later than 31 December 1997.

*Deliberated in public session, at Paris, 25 November 1992.*

*The President,*  
**Signed: HENRI EMMANUELLI**

**END OF TRANSLATION**

**FRANCE.** Decree No. 88-327 of 8 April 1988 on the activities involved in medically assisted procreation. (*Journal officiel de la République Française, Lois et Décrets*, 9 April 1988, No. 84, pp. 4707-4708)

Fr. 88.75

This Decree has been made in pursuance of, *inter alia*, certain provisions of Law No. 70-1318 of 31 December 1970 on the reform of the hospital system (*see IDHL*, 1971, 23, 222), as amended.

Secs. 1-6 read as follows:

"1. The activities involved in medically assisted procreation shall comprise:

1. the collection of human oocytes and the transfer of fertilized human ova; and
2. the collection of sperm, the treatment of human gametes with a view to fertilization, their preservation, *in vitro* fertilization, and preservation of fertilized human ova for implantation.

2. The licence referred to in the second paragraph of Section 34 and in the third paragraph of Section 48 of the above-mentioned Law of 31 December 1970 shall be subject to the following conditions:

1. in order to practise the activities defined in item 1 of Section 1, public and private hospital establishments to which the above-mentioned Law of 31 December 1970 applies shall satisfy the requirements of Sections 3 and 4; and
2. in order to practise the activities defined in item 2 of Section 1, public and private hospital establishments to which the above-mentioned Law of 31 December 1970 applies shall satisfy the requirements of Sections 3 and 4.

Before the Minister responsible for Health reaches a decision, consultations shall be held with the National Commission on Medical and Reproductive Biology, and thereafter with the National Commission on Health and Welfare Facilities.

3. An establishment or department in which the activities defined in item 1 of Section 1 are practised shall:

1. have on its staff at least one medical specialist in gynaecology or obstetrics with further training in reproductive medicine, failing which, experience deemed adequate by the National Commission on Medicine and Reproductive Biology; and
2. have access, in case of need, to a physician experienced in echography and an anaesthetist.

4. The premises on which the activities defined in item 1 of Section 1 are practised shall be located within a gynaecology and obstetrics unit; they shall comprise, as a minimum, a consulting room, an operating theatre, a recovery room, and hospitalization beds, and shall be equipped with at least one high-definition echography unit.

5. An establishment or department in which the activities defined in item 2 of Section 1 are practised shall have on its staff at least one person holding a diploma in further studies in reproductive biology and a doctorate (*thèse de troisième cycle*) in reproductive biology, or a physician who has obtained a qualification in the specialty of medical biology, or a *pharmacien biologiste*, failing whom, a person whose qualifications are deemed adequate by the National Commission on Medicine and Reproductive Biology.

In all these cases, the person in question shall have experience in the manipulation of human gametes that has undergone appraisal by the National Commission on Medicine and Reproductive Biology.

6. The premises on which the activities defined in item 2 of Section 1 are practised shall include, in addition to a laboratory as such, a room equipped for the ob-

lection of sperm, and a room equipped for the preservation of gametes and fertilized human ova; the latter room shall have equipment to prevent theft.

By way of exemption from the provisions of Section 4, fertilized ova may be transferred on the premises referred to in the preceding paragraph, in a separate room, equipped for this purpose; they may only be transferred by a physician."

Sec. 8 defines the conditions under which clinical laboratories may practise the activities referred to in item 2 of Sec. 1, the licence being issued by decision of the Minister responsible for Health, after consulting the National Commission on Medicine and Reproductive Biology and the Standing National Commission on Medical Biology.

**FRANCE.** Decree No. 88-328 of 8 April 1988 establishing the National Commission on Medicine and Reproductive Biology. (*Journal officiel de la République française, Lois et Décrets*, 9 April 1988, No. 84, pp. 4708-4709) **Fr. 88.76**

This Decree has been made in pursuance of, *inter alia*, certain provisions of Law No. 70-1318 of 31 December 1970 on the reform of the hospital system (see *IDHL*, 1971, 22, 222), as amended. Sec. 1 establishes the Commission referred to in the title; it consists of two Sections, viz. the Section for Prenatal Diagnosis and the Section for Medically Assisted Procreation. Secs. 2-5 specify the members of these Sections, which comprise *ex officio* members and members appointed by the Minister responsible for Health. Secs. 6-13 deal with the functions and working procedures of the Commission, the former Section being consulted for decisions taken by the Minister responsible for Health concerning the practice of examinations carried out in connection with prenatal diagnosis and the latter Section being consulted on the issue, suspension, or withdrawal of the licence referred to in Sec. 2 of Decree No. 88-327 of 8 April 1988 (see *supra*) and on granting of exemptions as referred to in Sec. 7 of that Decree. Sec. 14 lays down that the Minister is to transmit to the Commission reports and documents, particularly of a statistical nature, concerning the practice of prenatal diagnosis and activities involved in medically assisted procreation.

**FEDERAL REPUBLIC OF GERMANY.** Law of 13 December 1990 for the protection of embryos (the Embryo Protection Law).<sup>a</sup> (*Bundesgesetzblatt*, Part 1, 19 December 1990, pp. 2746-2748) **FRG 91.9**

*Improper use of reproductive technologies*

1. (1) A penalty of up to three years' imprisonment or a fine shall be imposed on any person who:

1. transfers, into a woman, an unfertilized egg cell produced by another woman;
2. attempts to fertilize artificially an egg cell for any purpose other than bringing about a pregnancy of the woman from whom the egg cell originated;
3. attempts, within one treatment cycle, to transfer more than three embryos into a woman;
4. attempts, by means of gamete intrafallopian transfer, to fertilize more than three egg cells within one treatment cycle;
5. attempts to fertilize more egg cells from a woman than may be transferred to her within one treatment cycle;
6. removes an embryo from a woman before completion of implantation in the uterus, with a view to transferring it to another woman or to using it for another purpose that is not conducive to its preservation; or
7. attempts to carry out artificial fertilization of a woman who is prepared to give up her child permanently after birth (surrogate mother) or to transfer a human embryo into her.

(2) The same penalty shall be imposed on any person who:

1. brings about artificially the penetration of a human egg cell by a human sperm cell; or
2. transfers a human sperm cell into a human egg cell artificially, without intending to bring about a pregnancy in the woman from whom the egg cell originated.

(3) No penalties shall be imposed on:

1. in the case of items 1, 2, and 6 of subsection 1, the woman from whom the egg cell or embryo originated, as well as the woman into whom the egg or embryo are to be transferred; and
2. in the case of item 7 of subsection 1, the surrogate mother as well as the person wishing to assume responsibility for the long-term care of the child.

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<sup>a</sup> This translation is partly based on a translation published in the *Bulletin of Medical Ethics*, December 1990, No. 64, pp. 9-11. Permission to use this translation was kindly granted by the Editor, Dr Richard Nicholson, and by Professional and Scientific Publications Ltd, London. — ED

(4) In the case of item 6 of subsection 1 and Section 2, attempts shall be punishable.

*Improper use of human embryos*

2. (1) Any person who transfers a human embryo that is derived from extracorporeal procreation or that has been removed from a woman before its nidation in the uterus, or who disposes of, acquires, or uses it for a purpose other than its preservation, shall be punished by up to three years' imprisonment or by a fine.

(2) The same penalty shall be imposed upon any person who is responsible for the extracorporeal development of a human embryo, for purposes other than pregnancy.

(3) Attempts shall be punishable.

*Prohibited sex selection*

3. Any person who attempts to artificially fertilize a human egg cell with a sperm cell, that is selected for the sex chromosome contained in it, shall be punished by up to one year's imprisonment or by a fine. This shall not apply if the selection of a sperm cell is made by a physician in order to prevent the child from developing Duchenne-type muscular dystrophy or a sex-linked hereditary disease of similar severity, and if the disease threatening the child is recognized as being of appropriate severity by the authority that is competent for this matter under *Land* law.

*Unauthorized fertilization, unauthorized embryo transfer, and artificial fertilization after death*

4. (1) A penalty of up to three years' imprisonment or a fine shall be imposed on any person who:

1. attempts to artificially fertilize an egg cell without the woman whose egg cell is to be fertilized, and the man whose sperm cell is to be used for fertilization, having given consent;
2. attempts to transfer an embryo into a woman without her consent; or
3. knowingly fertilizes artificially an egg cell with the sperm of a man after his death.

(2) In the case of item 3 of subsection 1, no penalties shall be imposed on the woman upon whom the artificial fertilization was performed.

*Artificial alteration of human germline cells*

5. (1) Any person who artificially alters the genetic information of a human germline cell shall be punished by up to five years' imprisonment or by a fine.



(2) The same penalty shall be imposed on any person who uses a human germ cell with artificially modified genetic information for fertilization.

(3) Attempts shall be punishable.

(4) Subsection 1 shall not apply to:

1. the artificial modification of the genetic information of a germline cell situated outside the body, if there is no possibility of its being used for fertilization;

2. the artificial modification of the genetic information of germline cells from a different body, that have been removed from a dead conceptus, from a living person, or from a deceased person, if there is no possibility that:

(a) they will be transferred to an embryo, fetus, or human being, or

(b) a germ cell will develop from them; and

3. vaccination, radiation, chemotherapeutic, or other treatments, by which a modification of the genetic information of germline cells is not intended.

#### *Clones*

6. (1) Any person who artificially causes a human embryo to develop with the same genetic information as another embryo, fetus, living person, or deceased person shall be punished by up to five years' imprisonment or by a fine.

(2) The same penalty shall be imposed on a person who transfers an embryo as specified in subsection 1 into a woman.

(3) Attempts shall be punishable.

#### *Creation of chimeras and hybrids*

7. (1) A penalty of up to five years' imprisonment or a fine shall be imposed on any person who attempts:

1. to unite in one syncytium embryos with different genetic information, involving the use of at least one human embryo;

2. to combine a human embryo with a cell that contains different genetic information from the embryo cells, and which is capable of subsequent differentiation; or

3. by fertilization of a human egg cell with the sperm of an animal or by fertilization of an animal's egg cell with the sperm of a man, to produce an embryo capable of differentiation.

(2) The same penalty shall be imposed on any person who attempts:

*International Digest of Health Legislation, 1991, 42 (1)*

1. to transfer an embryo produced by a procedure as specified in subsection 1 into:
  - (a) a woman; or
  - (b) an animal; or
2. to transfer a human embryo into an animal.

#### *Definitions*

8. (1) For the purpose of this Law, the term "embryo" means the human egg cell, fertilized and capable of development, from the time of fusion of the nuclei, as well as each totipotent cell removed from an embryo that is capable, in the presence of other necessary conditions, of dividing and developing into an individual.

(2) In the first 24 hours after fusion of the nuclei, the fertilized human egg cell shall be considered to be capable of development, unless it is established before the end of this period that it is not capable of developing beyond the single-cell stage.

(3) "Germline cells", for the purposes of this Law, means all cells that lead in a cell line from the fertilized egg cell to the egg cells and sperm cells of the human being produced, as well as the egg cell from the moment of introduction or penetration of the sperm cell to the completion of fertilization through the fusion of nuclei.

#### *Medical proviso*

9. Only a physician may carry out:
1. artificial fertilization;
  2. the transfer of a human embryo into a woman; and
  3. the preservation of a human embryo or a human egg cell which has already been penetrated by, or has had artificially introduced into it, a human sperm cell.

#### *Voluntary participation*

10. No person shall be obliged to carry out or take part in the procedures described in Section 9.

#### *Violation of the medical proviso*

11. (1) A penalty of up to one year's imprisonment or a fine shall be imposed upon any person who, without being a physician:

1. carries out artificial fertilization contrary to item 1 of Section 9; or
2. transfers a human embryo into a woman contrary to item 2 of Section 9.

NORWAY. Law No. 68 of 12 June 1987 on artificial fertilization. (*Norsk Lovtidend*, Section I, 26 June 1987, No. 13, pp. 502-503)<sup>1</sup>  
Norw. 87.27

### Chapter I

#### General provisions

1. In this Law, "artificial fertilization" means artificial insemination and fertilization outside the human body.

2. Artificial fertilization may be carried out only in institutions specially approved for this purpose by the Ministry [of Social Affairs]. Every institution in which artificial fertilization is carried out must submit a written report on its activities to the Ministry. The Ministry shall issue detailed rules on the reporting procedures.

3. Only establishments which, in accordance with the provisions of Section 2, are authorized to undertake artificial fertilization, may freeze sperm or store it in any other manner. The importation of sperm shall be subject to the authorization of the Directorate of Health.

The freezing of unfertilized eggs shall be prohibited.

Only establishments which, in accordance with the provisions of Section 2, are authorized to carry out artificial fertilization, may freeze fertilized eggs. The latter may be utilized only for implantation in women and may not be preserved for more than 12 months.

Research on fertilized eggs shall be prohibited.

4. Artificial fertilization may be carried out only in married women.

Prior to undertaking such treatment, the written consent of the woman and her husband shall be obtained.

5. The decision to undertake treatment to bring about artificial fertilization shall be taken by a physician. The decision shall be taken on the basis of medical and psychosocial assessments of the couple.

The couple shall be given information on the treatment and on the medical and legal effects which may follow from the treatment.

6. The Crown may issue provisions setting out more detailed conditions applicable to artificial fertilization.

### Chapter II

#### Artificial insemination

7. In this Law, "artificial insemination" means the introduction of semen into the woman's womb or cervix by means other than through sexual intercourse.

8. Artificial insemination may be carried out only when the husband is sterile or the carrier of a serious hereditary disease.

9. The attending physician shall select a suitable semen donor.

10. Health care staff shall be under a duty to ensure that the identity of the semen donor is kept secret. A semen donor may not be given information on the identity of the couple or child.

*International Digest of Health Legislation*, 1987, 38 (4)

*Chapter III**Fertilization outside the body*

11. In this Law, "fertilization outside the body" means the fertilization of an egg outside the body of a woman.

12. Fertilization outside the body may only be carried out if the woman is sterile. Such treatment may only be carried out with the gametes of the couple themselves.

The fertilized egg may be placed only in the woman in whom it originated.

*Chapter IV**Other provisions*

13. The Crown may issue detailed provisions for the implementation of this Law.

14. Persons intentionally carrying out artificial fertilization, using eggs or semen, or engaging in research contrary to this Law shall be liable to a fine or to imprisonment for a period not exceeding ~~one~~ months. Accomplices shall be liable to the same penalties.

If one of the offences mentioned in the foregoing paragraph is committed by a person acting on behalf of a company, association or institution, the state, commune, or other public agency, the undertaking or public agency shall be liable to a fine.

15. This Law shall enter into force on a date to be determined by the Crown. From that date the following amendments shall take effect in relation to other Laws:

1. Section 9a of Law No. 57 of 19 June 1969 on hospitals [see *IDHL*, 1970, 21, 818] is repealed.

2. The third and fourth paragraphs of Section 9 of Law No. 7 of 8 April 1981 on parents and children (the Children's Law) shall be amended to read as follows:

"If artificial insemination is carried out on the mother and the husband has given his consent to the insemination, he shall be deemed the father, provided that no reasonable doubt exists that the child was conceived through the insemination.

The semen donor may not be deemed to be the father. Nevertheless, this does not apply provided that the insemination is carried out using semen from the husband and no reasonable doubt exists that the child was conceived through the insemination."

**SPAIN.** Law No. 42/1988 of 28 December 1988 on the donation and use of human embryos and fetuses or their cells, tissues, or organs. (*Boletín Oficial del Estado*, 31 December 1988, No. 314, pp. 36766-36767) Sp. 91.1

## **CHAPTER I**

### **General principles**

1. The donation and use of human embryos and fetuses, or their cells, tissues and organs, for diagnostic, therapeutic, research, or experimental purposes, may be authorized only under the conditions laid down by this Law.

2. The donation and use of human embryos or fetuses, or their biological structures, for the purposes prescribed in this Law, may be effected provided the following conditions are fulfilled:

- (a) the donors must be the progenitors;
- (b) the donors have given their prior written consent, such consent being free, express, and informed. If the donors are unemancipated or incompetent minors, the consent of their legal representatives shall also be necessary;
- (c) the donors and, where appropriate, their legal representatives, are informed in advance of the possible consequences and of the objectives of the said donations;
- (d) the donation and subsequent utilization are not conditional upon any financial or commercial elements;
- (e) the embryos or fetuses involved in the donation are clinically unviable or dead; and
- (f) in cases where the progenitors have died and there is no legal record of their having indicated their express opposition. If the de-

*International Digest of Health Legislation*, 1991, 42 (1)

ceased progenitors were minors, the consent of their parents or guardians shall also be required.

In the case of accidental death, the donation must also be authorized by the judge in charge of the case.

3. (1) The use of human embryos or fetuses or of their biological structures shall be carried out by fully qualified biomedical teams at centres or services that are authorized and supervised by the public authorities.

(2) The termination of a pregnancy may never have as its objective the donation and subsequent utilization of the embryo or fetus, or their biological structures.

(3) The medical team that performs a pregnancy termination may not be involved in the utilization of the embryo or fetus or their biological structure under the conditions and for the purposes provided for in this Law.

4. (1) The utilization of embryonic or fetal cells, tissues, and organs for transplantation into patients may only be undertaken if the recipient has given his consent after having been informed of the aims, therapeutic possibilities, and the risks involved, and has accepted them in advance in writing.

(2) If the recipient is a minor or an incompetent, the consent of his parents or legal representative shall be required; in their absence, and in cases of emergency, consent shall be required from close family members.

## CHAPTER II

### Procedures undertaken with embryos and fetuses

5. (1) Any procedures performed on an embryo or live fetus *in utero* shall be of a purely diagnostic or therapeutic character or in accordance with the legal provisions in force.

(2) The progenitors shall be duly informed in advance as shall, where appropriate, those legally responsible, of technical procedures that are performed to extract embryonic or fetal cells or structures from the placenta or its membranes as well as the objectives pursued and the risks entailed.

(3) Aborted embryos, regardless of whether the abortion was spontaneous or not, shall be considered as unviable for the purposes of this Law in the light of their degree of development.

(4) Prematurely and spontaneously expelled fetuses considered to be biologically viable shall be treated clinically solely for the purposes of favouring their development and autonomous life.

6. The procurement and use of biological structures derived from dead embryos and fetuses for diagnostic, therapeutic, pharmacological,

clinical, surgical, investigational, or experimental purposes, as well as their donation for such purposes, shall be authorized subject to the provisions of this Law. Before carrying out such interventions, the medical teams concerned must certify that death of the embryo or fetus has occurred.

### CHAPTER III

#### Research, experimentation, and genetic technology

7. (1) Basic research on human embryos and fetuses or their biological structures shall be authorized only if it is in compliance with the provisions of this Law and is based on duly formulated protocols that have been examined, and, where appropriate, approved by the public authorities responsible for health and scientific affairs, or, if so delegated, by the National Commission for Supervision and Control of the donation and utilization of human embryos and fetuses.

(2) The teams responsible for research and/or experimentation shall communicate the results to the authorities which approved the corresponding protocol either directly, or in cases where this is required by regulations, through the National Commission for Supervision and Control.

8. (1) Genetic technology using human or combined genetic materials may be performed under the conditions laid down in this Law, and the provisions issued for its implementation, on the basis of appropriately formulated and authorized protocols, in which the location, duration, biological materials to be used, and objectives being pursued are stipulated.

(2) The application of genetic technology may be authorized in order to pursue the following objectives, under the conditions indicated:

(a) for diagnostic purposes in respect of genetic or hereditary diseases, i.e. in the context of *in vitro* or *in vivo* prenatal diagnosis, in order to avoid the transmission of such diseases or to treat or cure them;

(b) for industrial purposes having a preventive, diagnostic, or therapeutic character, such as the production, by molecular or gene cloning, of substances or products for public health or clinical use in sufficient amounts and in the absence of any biological hazard, where this cannot be achieved conveniently by other means, such as hormones, blood proteins, agents controlling the immune response, antivirals, antibacterials, antineoplastic agents, or vaccines where there are no immune or infective hazards;

(c) for therapeutic purposes, principally for sex selection in the event of diseases linked to the sex chromosomes, particularly chromosome X, thereby avoiding their transmission; or to create beneficial genetic mosaics through surgery, by transplanting cells, tissues, and or-

gans from embryos and fetuses into patients in which these are biologically and genetically modified or lacking; and

(d) for purposes of research on and studies of DNA sequences of the human genome, their location, functions, and pathology; for studies of recombinant DNA inside human cells or simple organisms, with the objective of enhancing knowledge of molecular recombination, expression of genetic messages, development of cells and their structures, as well as their dynamic processes and organization, the processes of aging of cells, tissues, and organs, and the general mechanisms of the aetiology of diseases, *inter alia*.

#### CHAPTER IV

##### Offences and penalties

9. ....

##### ADDITIONAL PROVISIONS

1. Within six months following the promulgation of this Law, the Government shall lay down:

(a) the requirements to be fulfilled as regards the authorization and functioning of centres, services, and biomedical teams associated with the donation and utilization of embryos or fetuses, or their biological materials, as well as of banks in which the latter are deposited and/or preserved;

(b) a list of the diseases of the embryo or fetus that are amenable to specific or gene therapy, and an inventory of the modes of utilization of embryonic or fetal materials for the treatment of diseases in other persons;

(c) the protocols that must be presented by persons performing the donation of embryos or fetuses or their biological materials for clinical or scientific purposes, and which must be signed prior to the granting of authorization;

(d) adequate means for the provision of general information on the donation and use of the above-mentioned biological materials, aimed particularly at facilitating the work of centres or services in which the donation or utilization of embryos, fetuses, or their parts are performed;

(e) criteria for determining the viability or non-viability of the fetus *ex utero*, for the purposes of this Law;

(f) requirements regarding the establishment, operation, and delegations of authority or areas of competence of the National Commission for Supervision and Control of the donation and utilization of human embryos and fetuses; and

(g) rules governing the interchange and circulation of embryonic or fetal materials at the national or international level.



SPAIN. Law No. 35/1988 of 22 November 1988 on assisted reproduction procedures.\* (*Boletín Oficial del Estado*, 24 November 1988, No. 282, pp. 33373-33378) Sp. 89.14

### Chapter I

#### Field of application of procedures for assisted human reproduction

1. (1) This Law regulates the following procedures (*técnicas*) for assisted human reproduction: artificial insemination (AI), *in vitro* fertilization (IVF), with embryo transfer (ET) and gamete intra-fallopian tube transfer (GIFT), when they are scientifically and clinically indicated and performed in authorized and accredited health and scientific centres and establishments by specialized teams.
- (2) Assisted reproduction procedures shall have as their aim medical action in the face of human sterility, with a view to facilitating procreation when other therapies have been excluded as inadequate or ineffective.
- (3) These procedures may also be used in the prevention and treatment of diseases of hereditary or genetic origin when there are sufficient diagnostic and therapeutic assurances and they are strictly indicated.
- (4) Research and experimentation on human gametes and fertilized ova may be authorized under the conditions laid down in Sections 14, 15, 16, and 17 of this Law.

### Chapter II

#### General principles

2. (1) Assisted reproduction procedures may be employed only:
  - (a) when there are reasonable prospects of success and they pose no serious hazard for the health of the mother or of any resultant descendants; and
  - (b) in women who have reached the age of majority and are in good physical and mental health, provided they have sought and accepted such procedures freely and in awareness of the facts, having been duly informed in advance on the subject.
- (2) Sufficient information and advice to persons wishing to have recourse to these procedures, or to be donors, concerning the various aspects and possible implications of the procedures, as well as the foreseeable results and risks, shall be obligatory. The information shall extend to whatever biological, legal, ethical, or economic considerations are related to the procedures and shall be the responsibility of the

\* This translation is partly based on a translation of a draft version of the Law, prepared and kindly made available by the Max Planck Institute for Foreign and International Criminal Law, Freiburg-im-Breisgau, Federal Republic of Germany. — ED.

medical teams and the persons in charge of the health centres or services in which they are carried out.

- (3) The acceptance of the performance of these procedures shall be indicated in a standard form recording all the circumstances that affect their application.
- (4) A woman who is a recipient of such procedures may request that they be suspended at any time while they are being performed, and her request shall be complied with.
- (5) All data concerning the use of these procedures shall be recorded in individual clinical case histories, which shall be treated with the necessary discretion, with strict secrecy as to the identity of the donors, the sterility of the users, and the circumstances of the origin of the children thus born.
3. The fertilization of human ova for any purpose other than human procreation shall be prohibited.
4. Only the number of pre-embryos considered scientifically to be the most appropriate for a reasonable prospect of pregnancy shall be transferred to the uterus.

### Chapter III

#### Provisions concerning donors

5. (1) The donation of gametes and pre-embryos for the purposes authorized by this Law shall form a gratuitous, formal, and secret contract entered into between the donor and the authorized centre.
- (2) The donation shall be revocable only when the donor, on account of sterility, requires the donated gametes for himself, always provided that they are available on the date of revocation. At the time of revocation, the donor shall reimburse all kinds of expenditure incurred by the recipient centre.
- (3) Donation shall never have a profit-making or commercial nature.
- (4) The contract shall be concluded in writing between the donor and the authorized centre. Prior to conclusion of the contract, the donor shall be informed of the purposes and consequences of the act.
- (5) The donation shall be anonymous, the particulars of the identity of the donor being kept in strictest secrecy and in coded form in the corresponding bank and in the National Register of Donors.  
The resultant children shall have the right, either personally or through their legal representatives, to obtain general information concerning the donors, although not including their identity. Recipients of gametes shall likewise have this right.  
Only in exceptional cases, in extraordinary circumstances that entail a verified danger to the life of the child, or under the law of criminal

procedure, may the identity of the donor be disclosed; it shall be a condition that such disclosure is indispensable to avert a danger or to attain the legal objective referred to. In such cases the provisions of subsection 3 of Section 8 shall be applicable. Disclosure shall be limited in character and shall under no circumstances make public the identity of the donor.

(6) The donor shall be more than 18 years of age and fully competent. His mental and physical state shall correspond to the terms of a compulsory study protocol on donors, which shall have a general character and include the phenotypic characteristics of the donor, as well as a determination certifying that he is not suffering from genetic, hereditary, or communicable diseases.

(7) Authorized centres and the National Register shall adopt appropriate measures and shall ensure that the same donor is not the progenitor of more than six children.

(8) The provisions of this Section shall be applicable to data concerning the provision of reproductive cells by the husband, when surplus (supernumerary) gametes are used for the fertilization of a person other than his wife.

#### Persons undergoing such procedures

6. (1) Every woman shall be entitled to undergo the procedures regulated by this Law, always on the condition that she has given her free and express consent to their use, in awareness of the facts, and in writing. She shall be at least 18 years of age and fully competent.

(2) A woman who wishes to undergo these assisted reproduction procedures shall be informed of the possible risks for her descendants and during her pregnancy resulting from her unsuitable age.

(3) If the woman is married, her spouse's consent shall likewise be required in accordance with the criteria laid down in the preceding subsection, unless they are separated either in accordance with a decree of divorce or judicial separation against which no appeal lies, or a *de facto* separation, or under a voluntary agreement which can be credibly established.

(4) The consent given by the husband prior to the use of these procedures, for the purposes referred to in subsection 2 of Section 8 of this Law, shall meet identical requirements as to free and express formulation, in awareness of the facts.

(5) The selection of the donor shall be the responsibility of the medical team carrying out the assisted reproduction procedure. It shall be guaranteed that the donor has the maximum phenotypic and immunological similarity [to the recipient] and is as compatible as possible with the recipient woman and her family environment.

*International Digest of Health Legislation*, 1999, 40 (1)

#### Parents and children

7. (1) The filiation of children born as a result of assisted reproduction procedures shall be regulated by the rules in force, without prejudice to the special provisions laid down in this Chapter.

(2) Registration in the registry office may under no circumstances provide information enabling any inference to be made concerning the mode of procreation.

8. (1) A husband or wife who has expressly consented in advance to a specific method of fertilization involving a contribution on the part of a donor or donors, may not contest the matrimonial filiation of a child born as a consequence of such fertilization.

(2)-(3) [Additional provisions concerning filiation and related matters]

9. (1)-(3) [Provisions governing filiation]

(4) Consent to the application of the procedures referred to may be withdrawn at any time prior to their application.

10. [Provisions concerning filiation]

#### Chapter IV

##### Cryopreservation and other procedures

11. (1) Semen may be kept under cryopreservation in authorized gamete banks for a maximum period of five years.

(2) The cryopreservation of oocytes for the purposes of assisted reproduction shall not be authorized, until such time as there are sufficient guarantees as to the viability of the oocytes after their defreezing.

(3) Surplus pre-embryos resulting from IVF that have not been transferred to a uterus may be kept under cryopreservation in authorized banks for a maximum period of five years.

(4) After two years of cryopreservation, gametes or pre-embryos that have not been claimed by the donors shall be at the disposal of the banks in question.

##### Diagnosis and treatment

12. (1) Any intervention on the live pre-embryo *in vitro* for diagnostic purposes may have as its sole objective the enhancement of its viability or the detection of hereditary diseases with a view to their treatment if this is possible, or with a view to advising against their transfer for purposes of procreation.

(2) Any intervention on the live embryo *in utero* or on the live fetus, either *in utero* or *ex utero*, for diagnostic purposes, shall be lawful only if its objective is the well-being of the child to be born and

*International Digest of Health Legislation*, 1999, 40 (1)

the enhancement of its development, or in the event that the procedure is specifically sanctioned by law.

13. (1) Any intervention upon the live pre-embryo *in vitro* for therapeutic purposes may have as its sole objective the treatment or the prevention of the spread of a disease, where there are reasonable and verified prospects of success.

(2) Any intervention on a live embryo or on a live fetus *in utero*, or on a viable fetus *ex utero*, may have as its sole therapeutic objective the enhancement of the well-being and the enhancement of the development of the embryo or fetus concerned.

(3) Therapeutic procedures on pre-embryos *in vitro*, or on pre-embryos, embryos, and fetuses *in utero*, shall be authorized only if they fulfil the following requirements:

(a) the couple or, as appropriate, the woman alone has been scrupulously informed on the procedures, diagnostic investigations, potentialities, and risks of the proposed therapy and has accepted them in advance;

(b) the diseases in question have a very precise diagnosis, a serious or very serious prognosis, and the prospects for an improvement or cure of the disorder are at least reasonable;

(c) a list of diseases in which therapy is possible, with strictly scientific criteria, is available;

(d) there is no influence on non-pathological hereditary traits, and no selection of individuals or of race is sought; and

(e) the procedure is performed in authorized health centres, by qualified teams with the necessary resources.

#### Research and experimentation

14. (1) Gametes may be independently used for purposes of basic or experimental research.

(2) Research directed towards improving the procedures used for obtaining oocytes and their maturation, and the procedures for the cryopreservation of ova, shall be authorized.

(3) Gametes used for research or experimentation made not be used to derive pre-embryos for purposes of procreation.

(4) It shall be authorized to use the hamster test to evaluate the capacity of fertilization of human spermatozoa until the phase of binary fission of the fertilized hamster ovule, at which time the test shall be interrupted. Other forms of fertilization between human and animal gametes shall be prohibited, unless permission has been granted by the competent public authority or, as appropriate, the National Multidisciplinary Commission, if delegated jurisdiction has been conferred on it.

*International Digest of Health Legislation, 1989, 48 (1)*

15. Research or experimentation on live pre-embryos shall be authorized only if the following requirements are met:

1. in the case of any research, either of a diagnostic or general nature, on pre-embryos, it shall be necessary that:

(a) the written consent of the persons in whom they originate, including, where appropriate, the donors, is obtained, after a prior detailed explanation of the objectives of the research and its implications;

(b) they do not develop *in vitro* for more than 14 days after fertilization of the ovule, deducting any time when they have been have been subject to cryopreservation; and

(c) the research is carried out in medical centres, by approved, qualified, and authorized multidisciplinary scientific teams, under the control of the competent public authorities;

2. research on pre-embryos *in vitro* shall be authorized only in the case of:

(a) applied research of a diagnostic character, for therapeutic or prophylactic purposes; and

(b) there are no modifications to the non-pathological genetic patrimony; and

3. research on pre-embryos for purposes other than the determination of their viability or diagnosis shall be authorized only in the following cases:

(a) the pre-embryos involved are non-viable;

(b) it has been demonstrated scientifically that the research cannot be conducted on animal models;

(c) the research is conducted on the basis of a protocol that has been duly presented to and authorized by the competent health and scientific authorities or, as appropriate, by delegation by the National Multidisciplinary Commission; and

(d) the research is performed within the prescribed time.

16. The following shall be authorized, subject to the conditions laid down in Sections 14 and 15 of this Law:

(a) the improvement of procedures for assisted reproduction and associated manipulations, cryopreservation, and defreezing of embryos, and techniques for acquiring better knowledge of the criteria of viability for pre-embryos obtained *in vitro* and the optimum timing for their transfer to the uterus;

(b) basic research on the origin of human life in its initial phases, cellular aging, and cell division, meiosis, mitosis, and cytokinesis;

*International Digest of Health Legislation, 1989, 48 (1)*

- (c) research on the processes of differentiation, cellular organization, and development of the pre-embryo;
  - (d) research on male and female fertility and infertility, the mechanisms of ovulation, failures in the development of oocytes or the implantation of fertilized ova in the uterus, and anomalies in gametes and fertilized ova;
  - (e) research on the structure of genes and chromosomes, their localization, identification, and functioning, as well as the processes of sexual differentiation in the human being;
  - (f) research on contraception or "anti-conception", such as research connected with the formation of antibody modifiers of the pellucid zone of the ovule, contraception of immunological origin, male contraception, or contraception originating in hormonal implants with continued and lasting action;
  - (g) research on histocompatibility or immunological phenomena, including the phenomena of rejection between the sperm and/or fertilized ova and the vaginal medium, the neck (cervix) of the uterus, or the uterine mucosa;
  - (h) research on hormonal action on the processes of gametogenesis and development;
  - (i) research on the origin of cancer and, in particular, chorioepithelioma (choriocarcinoma);
  - (j) research on the origin of genetic and hereditary diseases, such as chromosomal abnormalities, metabolic diseases, infectious diseases, or diseases introduced by external agents (mutagenic, teratogenic, physical, chemical, and others), and in particular very serious diseases; and
  - (k) any other research duly authorized by regulations or, failing such regulations, by the National Multidisciplinary Commission.
- (2) Experimentation on live pre-embryos obtained *in vitro*, whether or not they are viable, shall be prohibited until it is proved scientifically that animal models are inadequate for the purpose. If it is demonstrated in specific experimental protocols that animal models are invalid, experimentation on non-viable human pre-embryos may be authorized by the competent authorities or, if so delegated, by the National Multidisciplinary Commission.
- (3) Any project for experimentation on non-viable pre-embryos *in vitro* shall be duly documented as regards the embryological material to be used, its provenance, the time-limits within which the experimentation is to be conducted, and the objectives pursued. Once the authorized project has been terminated, the results of the experimentation shall be transmitted to the authority that granted authorization.
- (4) Experimentation on pre-embryos in the uterus or in the fallopian tubes shall be prohibited.

*International Digest of Health Legislation, 1989, 40 (1)*

17. (1) Aborted pre-embryos shall be considered dead or non-viable and shall under no circumstances be returned to the uterus but may be subject to research and experimentation under the terms of this Law.
- (2) The use of non-viable human pre-embryos for pharmaceutical, diagnostic, or therapeutic purposes shall be permitted, provided that these purposes are known in advance and have been authorized.
- (3) The use of dead pre-embryos for scientific, diagnostic, or therapeutic purposes shall be authorized.

## Chapter V

### Health centres and biomedical teams

18. All centres or services in which the procedures for assisted reproduction, or subsidiary procedures, are performed, including banks for the receipt, preservation, and distribution of human biological materials, shall be considered public or private health centres or services, and shall be governed by the provisions of the General Law on Health [No. 14/1986 of 25 April 1986 (see *IDL*, 1987, 38, 1, Sp. 87.18)] and the regulations made for its implementation or in accordance with the [decisions of] the public administrations responsible for health matters.
19. (1) Biomedical teams working in such health centres or services shall be specially qualified to perform procedures for assisted reproduction, their associated applications, or related scientific activities, and shall for this purpose have the necessary equipment and resources. They shall work in an interdisciplinary manner, and the director of the centre or service to which they are subordinate shall be directly responsible for their activities.
- (2) Biomedical teams and the management of the centres or services in which they work shall be responsible under law if they violate secrecy as regards the identity of the donors, if the procedures employed in assisted reproduction or the corresponding biological materials constitute malpractice, or if, due to omission of information or protocolized studies, they harm the interests of donors or users, or if congenital or hereditary diseases, avoidable by such prior information and studies, are transmitted to descendants.
- (3) Medical teams shall record, in a case history to be retained with due secrecy and protection, all necessary particulars concerning donors and users, as well as signed consent forms for the performance of the donation or of the procedures.
- (4) Biomedical teams shall perform on donors and recipients all studies listed in protocols in accordance with regulations.
- (5) [Provisions corresponding to those of subsection 2]
- (6) Medical teams shall record, in a case history, to be retained with due secrecy and protection, all necessary particulars concerning donors,

*International Digest of Health Legislation, 1989, 40 (1)*

recipients, and, where appropriate, the husband or stable partner of the woman in question, as well as signed consent forms for the performance of the donation or the procedures.

(7) Failure to take case histories or omission of the specified references, data, or consents, shall entail liability on the part of the biomedical teams and the centres or services in which they work.

(8) Data in clinical histories, with the exception of the identity of donors and, if desired, the identity of recipients or of the husband or stable partner of the woman in question, shall be made available to the recipients or their partners, or to a resultant child on reaching the age of majority, if so requested.

## Chapter VI

### Offences and penalties

20. (1) Subject to the adaptations necessitated by the special features of the matters regulated by this Law, the rules governing contraventions and penalties laid down in Sections 32-37 of the General Law on health shall be applicable.

(2) In addition, to those indicated in the General Law on health, the following shall be considered serious and very serious offences for the purposes of the present Law:

#### (A) serious offences:

- (a) failure to comply with regulatory requirements for the operation of health centres and biomedical teams;
- (b) violation of the provisions of the General Law on health, the present Law, and the rules for its implementation, as regards the treatment of users of these procedures by work teams; and
- (c) the omission of data, consents, and references required by the present Law, as well as failure to take a case history;

#### (B) very serious offences:

- (a) fertilizing human ova for any purposes other than human procreation;
- (b) obtaining human pre-embryos by uterine lavage for any purpose;
- (c) maintaining *in vitro* live fertilized ova, beyond the 14th day after fertilization, deducting any time during which they may have been subject to cryopreservation;
- (d) keeping pre-embryos alive for the purpose of obtaining usable specimens;
- (e) carrying on trade in, or the import or export of, pre-embryos or their cells;

(f) engaging in industrial use of pre-embryos or their cells, except for strictly diagnostic, therapeutic, or scientific purposes under the terms of this Law or the rules for its implementation, provided that these purposes cannot be achieved in any other way;

(g) using pre-embryos for cosmetic or similar purposes;

(h) mixing semen from different donors to inseminate a woman or to perform IVF, or using ova from different women in order to undertake IVF or GIFT;

(i) transferring to the uterus gametes or pre-embryos without the necessary biological or viability assurances;

(j) disclosing the identity of donors other than in the exceptions specified by this Law;

(k) creating identical human beings by cloning or other procedures directed to selection of traits;

(l) creating human beings by cloning in any of its variants, or any other procedure capable of yielding several identical human beings;

(m) effecting parthenogenesis or stimulation of the development of an ovule by thermal, physical, or chemical methods, without its having been fertilized by a spermatozoon, thereby producing solely female progeny;

(n) effecting selection of sex or genetic manipulation for non-therapeutic purposes or for therapeutic purposes that are unauthorized;

(o) creating pre-embryos from persons of the same sex, for reproduction or other purposes;

(p) fusing pre-embryos with each other, or any other procedure directed to producing chimeras;

(q) carrying out human genetic interchange, or recombination with other species in order to produce hybrids;

(r) transferring human gametes or pre-embryos to the uterus of another animal species, or the reverse operation, if these are unauthorized;

(s) carrying out ectogenesis, or the creation of an individualized human being in the laboratory;

(t) creating pre-embryos with sperm from different persons with a view to their transfer to the uterus;

(u) transferring to the uterus, at the same time, pre-embryos derived from the ova of different women;

(v) employing genetic manipulation and other procedures for military or any other purposes, in order to produce biological weapons or weapons intended for the extermination of the human species, irrespective of their type; and

(x)\* carrying on research or experimentation that does not conform to the provisions of this Law or the rules for implementation.

(3) Whenever offences on the part of health personnel assigned public centres occur, the provisions as to liability shall conform with the relevant disciplinary rules for personnel in the service of the Public Administration.

## Chapter VII

### National Commission on Assisted Reproduction

21. (1) The Government shall establish, by Crown decree, a permanent agency, the National Commission on Assisted Reproduction, with a view to providing guidance on the utilization of these procedures, collaborating with the Administration in the compilation and updating of scientific and technical knowledge, and in the formulation of criteria for the operation of centres or services in which assisted reproduction procedures are performed, with a view to their optimal utilization.

(2) The National Commission on Assisted Reproduction may, in the absence of relevant regulations, have delegated functions enabling it to authorize scientific, diagnostic, therapeutic, research, and experimental projects.

(3) The National Commission on Assisted Reproduction shall be constituted by: representatives of the Government and the Administration; representatives of the various associations concerned with human fertility and these procedures; and a Council whose membership has a broad social spectrum.

(4) As soon as the areas of jurisdiction and functions of the National Commission on Assisted Reproduction have been determined by the Government, the Commission shall draw up its own rules and regulations, which shall be subject to approval by the Government.

### Transitional provision

Within a period of six months, and in accordance with criteria laid down in the General Law on health, the Government shall regulate and harmonize the terms of this Law insofar as it affects the Autonomous Communities.

### Final provisions

*[Enumeration of matters to be covered by Crown decree, made within six months following the promulgation of this Law; establishment of a computerized National Register of donors of gametes and pre-embryos for purposes of human reproduction; etc.]*

\* There is no "w" in the Spanish language. — ED.

**SWEDEN.** Law No. 711 of 14 June 1988 on fertilization outside the human body. (*Svensk författningssamling*, 1988, 22 June 1988, 1 p.)  
Swed. 89.28

1. This Law shall apply to the fertilization of a woman's egg outside her body, for the purpose of producing a child.
2. An egg which has been fertilized outside the body of a woman may not be introduced into her body unless:
  1. the woman is married or living in a state of cohabitation;
  2. the husband or cohabitant gives his written consent; and
  3. the egg is the woman's own and has been fertilized with the sperm of her husband or cohabitant.
3. Unless the authorization of the National Board of Health and Welfare is obtained, fertilization outside the human body may only be carried out in a general hospital.
4. Persons committing a breach of Sections 2 or 3 habitually or for gain shall be liable to a fine or to a prison sentence not exceeding six months.

See also p. 75 (Alg. 89.10), p. 81 (Niger 89.12)

**SWEDEN.** Regulations and General Recommendations No. 35 of 30 November 1989 of the National Board of Health and Welfare on extra-corporeal fertilization, etc. (*Socialstyrelsens författningssamling*, 1989, 8 February 1990, 16 pp.)  
Swed. 91.13

This text recalls the provisions of Law No. 711 of 14 June 1988 on *in vitro* fertilization (see *IDHL*, 1989, 40, 93, Swed. 89.28), and is a follow-up to Regulations and General Recommendations No. 6 of 27 March 1987 of the National Board of Health and Welfare on artificial insemination (see *ibid*, 1988, 39, 81, Swed. 88.29). It supplements the latter by dealing, in greater detail, with the psychological aspects of involuntary infertility, being addressed primarily to medical and nursing personnel.

It comprises the following rubrics: 1. Introduction; 2. Involuntary infertility; 3. Methods of extracorporeal fertilization [IVF, GIFT, and ZIFT]; 4. Freezing and storage of fertilized eggs; 5. Consent; 6. Information and counselling; 7. Competence and reporting; 8. Paternity of children resulting from extracorporeal fertilization; and 9. Penal provisions.

The regulatory provisions contained in rubrics 4, 5, and 7 read as follows:

**Rubric 4**

"The National Board of Health and Welfare hereby prescribes as follows:

- storage shall be effected in such a way that there can be no doubt as to the identity of eggs, sperm, or fertilized eggs;
- in the event of the man's death, his sperm may not be utilized for extra-corporeal fertilization. Similarly, any egg that he may have fertilized may not be implanted in a woman."

**Rubric 5**

"The National Board of Health and Welfare hereby prescribes as follows:

- it shall be essential to have the written consent of the man and woman in those aspects that concern them, whether this relates to the freezing of sperm, fertilized eggs, or unfertilized eggs, or research on methods; and
- written consent to IVF (or, as appropriate, GIFT or ZIFT), freezing, and/or research on methods shall be recorded in the woman's file."

*Rubric 7*

"The National Board of Health and Welfare hereby prescribes as follows:

- the physician in charge of IVF activities shall be a specialist in obstetrics and gynaecology;
- access to a professional in the field of psychology shall be essential. Any person, other than the physician responsible for counselling in psychology, shall possess qualifications corresponding to those of a social worker (*kurator*) or a psychologist;
- the health care unit shall possess the experience necessary for examining and treating involuntary infertility, knowledge of reproductive endocrinology, operative gynaecology, and ultrasound diagnosis in gynaecology, as well as appropriate competence in laboratory techniques, and up-to-date experience in *in vitro* techniques;
- the available resources must be such as to enable an emergency laparotomy to be carried out in connection with removal of the egg;
- any application addressed to the National Board of Health and Welfare by a private hospital with a view to performing IVF shall include a description of the intervention related to the above-mentioned requirements, as well as information on the scope of the projected intervention and on the available organizational structures and resources to undertake this intervention; and
- the results of activities in the above field performed in general or private hospitals shall be reported annually to the National Board of Health and Welfare using the prescribed form [Serial No. SOSB 37260; reproduced in an Annex to this text]."

**SWEDEN.** Law No. 115 of 14 March 1991 concerning measures for the purposes of research or treatment in connection with fertilized human oocytes. (*Svensk författningssamling*, 1991, 26 March 1991, 2 pp.)

Swed. 93.2

The principal provisions of this Law, which entered into force on 1 October 1991, read as follows:

"1. Within the meaning of this Law, measures involving fertilized oocytes of human origin shall be subject to the consent of the oocyte and sperm donors.

2. Any experimentation on fertilized oocytes for the purposes of research or treatment shall be carried out within a maximum period of 14 days from the time of fertilization. The purpose of experimentation shall not be to develop methods aimed at causing heritable genetic effects.

At the end of the period referred to in the preceding paragraph, any fertilized oocyte that has been used in experimentation shall be immediately destroyed.

3. Fertilized oocytes may be stored in the frozen state for a maximum period of one year, or for a longer period as specified by the National Board of Health and Welfare in accordance with Section 5.

The period during which the oocytes have been frozen shall not be taken into account when calculating the period during which an experiment is authorized under Section 2.

4. Fertilized oocytes that have been used in an experiment for the purposes of research or treatment may not be introduced into the body of a woman. The same provisions shall apply if the oocytes before fertilization, or the sperm used in fertilization, were used in an experiment.

5. Where there are valid grounds, the National Board of Health and Welfare may, in special cases, agree to extend the period of storage in the frozen state referred to in Section 3.



If it agrees to such an extension, the National Board of Health and Welfare shall determine the additional period for which storage is to be authorized.

This decision may be subject to certain conditions. It may be revoked if these conditions are not observed, or if there are other grounds for such revocation.

6. [Penal provisions]

7. Any decision taken by the National Board of Health and Welfare in pursuance of Section 5 may be the subject of an appeal brought before a court of appeal."

**SWEDEN.** Law No. 1956 of 19 December 1991 amending Law No. 133 of 1944 on castration. (*Svensk författningssamling, 1991, 30 December 1991, 1 p.*) Swed. 93.5

Sec. 4 of Law No. 133 of 24 March 1944 is amended to read substantially as follows:

"4. Unless otherwise provided for in this Law, castration may not be performed unless it is authorized by the National Board of Health and Welfare. Such authorization shall only be granted if the person concerned, where appropriate, has had the opportunity to express his opinion on the matter; if he is a minor, such opinion shall be sought from his guardian; if he is married, from his spouse; and if he is hospitalized, from the physician or director of the establishment concerned.

If a person has reached the age of 23 years and is able to give valid consent, castration may be performed in accordance with subsection 2 of Section 1, without the prior authorization of the National Board of Health and Welfare, if the physician carrying out the operation and another physician of the rank prescribed by the Government submit a written report indicating the grounds for such measures and certifying that, to the best of their knowledge and belief, the necessary conditions are fulfilled. These provisions shall not, however, be applicable to a person admitted to a correctional facility, a prison, an institution in pursuance of the provisions of Law No. 670 of 1988 on the care of drug-dependent persons in certain cases, or a care establishment in pursuance of the provisions of Law No. 1128 of 1991 on compulsory psychiatric care or Law No. 1129 of 1991 on legal psychiatric care.

....."

**SWEDEN.** Order No. 15 of 30 September 1992 of the National Board of Health and Welfare amending the Regulations and General Recommendations of the National Board of Health and Welfare (SOSFS 1989: 35) on extracorporeal fertilization. (*Socialstyrelsens författningssamling, 1992, 14 October 1992, 4 pp.*) Swed. 93.6

This Order is a follow-up to Law No. 115 of 14 March 1991 (see *supra*) and amends Regulations and General Recommendations No. 35 of 30 November 1989 (see *IDHL, 1991, 42, 68, Swed. 91.13*). The Annex to the Order consists of a model of the form to be used for the annual report submitted by establishments with regard to extracorporeal fertilization.

**SWITZERLAND.** Genetics and assisted procreation. Amendment of Federal Constitution. Dated 13 August 1992. (*Recueil officiel des lois fédérales*, 25 August 1992, No. 32, pp. 1579-1580) **Switz. 92.9**

The Federal Constitution of 29 May 1874 is amended by the insertion of the following new Sec. 24 *novies* (with effect from 17 May 1992):

"24 *novies*. (1) Man and the environment shall be protected against abuses in the field of procreation and genetic engineering techniques.

(2) The Confederation shall issue provisions concerning the use of the germ-cell and human genetic heritage [*patrimoine*]. It shall thereby endeavour to ensure the protection of human dignity, personality, and the family and shall conform, in particular, to the following principles:

(a) interventions affecting the genetic heritage of human gametes and embryos shall not be admissible;

(b) the germ-cell and genetic heritage of non-human species may not be transferred to the human germ-cell heritage, nor fused with it;

(c) the use of methods of assisted procreation shall only be authorized when sterility or the risk of transmission of a serious disease cannot be avoided in any other manner; they shall not be authorized in order to develop certain characteristics in the child, or for research purposes. The fertilization of human ova outside the woman's body shall only be authorized under the conditions laid down by law. Only the number of human ova that may be immediately implanted may be developed as far as the embryo stage, outside the woman's body;

(d) embryo donation and all forms of surrogate motherhood shall be prohibited;

(e) the human germ-cell heritage and products derived from embryos may not be the subject of commerce;

(f) the genetic heritage of a person may only be analysed, recorded, and disclosed with that person's consent, or on the basis of a legal provision; and

(g) a person shall be guaranteed access to data relating to his parentage.

(3) The Confederation shall issue provisions on the use of the germ-cell and genetic heritage of animals, plants, and other organisms. In doing so, it shall take into account the dignity of living beings [*creature*], and the safety of man, animals, and the environment; it shall also protect the genetic diversity of animal and plant species."

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## Human Fertilisation and Embryology Act 1990

1990 Chapter 37. An Act to make provision in connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish a Human Fertilisation and Embryology Authority; to make provision about the persons who in certain circumstances are to be treated in law as the parents of a child; and to amend the Surrogacy Arrangements Act 1985. [1 November 1990]

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

### *Principal terms used*

*Meaning of "embryo", "gamete" and associated expressions.*

1.—(1) In this Act, except where otherwise stated—

(a) embryo means a live human embryo where fertilisation is complete, and

(b) references to an embryo include an egg in the process of fertilisation, and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.

(2) This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body; and in this Act—

(a) references to embryos the creation of which was brought about *in vitro* (in their application to those where fertilisation is complete) are to those where fertilisation began outside the human body whether or not it was completed there, and

(b) references to embryos taken from a woman do not include embryos whose creation was brought about *in vitro*.

(3) This Act, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.

(4) References in this Act to gametes, eggs or sperm, except where otherwise stated, are to live human gametes, eggs or sperm but references below in this Act to gametes or eggs do not include eggs in the process of fertilisation.

*Other terms.*

2.—(1) In this Act —

“the Authority” means the Human Fertilisation and Embryology Authority established under section 5 of this Act,

“directions” means directions under section 23 of this Act,

“licence” means a licence under Schedule 2 to this Act and, in relation to a licence, “the person responsible” has the meaning given by section 17 of this Act, and

“treatment services” means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

(2) Reference in this Act to keeping, in relation to embryos or gametes, include keeping while preserved, whether preserved by cryopreservation or in any other way; and embryos or gametes so kept are referred to in this Act as “stored” (and “store” and “storage” are to be interpreted accordingly).

(3) For the purposes of this Act, a woman is not to be treated as carrying a child until the embryo has become implanted.

*Activities governed by the Act*

*Prohibitions in connection with embryos.*

3.—(1) No person shall—

- (a) bring about the creation of an embryo, or
- (b) keep or use an embryo,

except in pursuance of a licence.

(2) No person shall place in a woman—

- (a) a live embryo other than a human embryo, or
- (b) any live gametes other than human gametes.

(3) A licence cannot authorise—

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal,

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or

(d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

*Prohibitions in connection with gametes.*

4.—(1) No person shall—

- (a) store any gametes, or

(b) in the course of providing treatment services for any woman, use the sperm of any man unless the services are being provided for the woman and the man together or use the eggs of any other woman, or

(c) mix gametes with the live gametes of any animal, except in pursuance of a licence.

(2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

(3) No person shall place sperm and eggs in a woman in any circumstances specified in regulations except in pursuance of a licence.

(4) Regulations made by virtue of subsection (3) above may provide that, in relation to licences only to place sperm and eggs in a woman in such circumstances, sections 12 to 22 of this Act shall have effect with such modifications as may be specified in the regulations.

(5) Activities regulated by this section or section 3 of this Act are referred to in this Act as "activities governed by this Act".

*The Human Fertilisation and Embryology Authority, its functions and procedure*

*The Human Fertilisation and Embryology Authority.*

5.—(1) There shall be a body corporate called the Human Fertilisation and Embryology Authority.

(2) The Authority shall consist of—

(a) a chairman and deputy chairman, and

(b) such number of other members as the Secretary of State appoints.

(3) Schedule 1 to this Act (which deals with the membership of the Authority, etc.) shall have effect.

*Accounts and audit.*

6.—(1) The Authority shall keep proper accounts and proper records in relation to the accounts and shall prepare for each accounting year a statement of accounts.

(2) The annual statement of accounts shall comply with any direction given by the Secretary of State, with the approval of the Treasury, as to the information to be contained in the statement, the way in which the information is to be presented or the methods and principles according to which the statement is to be prepared.

(3) Not later than five months after the end of an accounting year, the Authority shall send a copy of the statement of accounts for that year to the Secretary of State and to the Comptroller and Auditor General.

(4) The Comptroller and Auditor General shall examine, certify and report on every statement of accounts received by him under subsection (3) above and shall lay a copy of the statement and of his report before each House of Parliament.

(5) The Secretary of State and the Comptroller and Auditor General may inspect any records relating to the accounts.

(6) In this section "accounting year" means the period beginning with the day when the Authority is established and ending with the following 31st March, or any later period of twelve months ending with the 31st March.

*Reports to Secretary of State.*

7.—(1) The Authority shall prepare a report for the first twelve months of its existence, and a report for each succeeding period of twelve months, and shall send each report to the Secretary of State as soon as practicable after the end of the period for which it is prepared.

(2) A report prepared under this section for any period shall deal with the activities of the Authority in the period and the activities the Authority proposes to undertake in the succeeding period of twelve months.

(3) The Secretary of State shall lay before each House of Parliament a copy of every report received by him under this section.

*General functions of the Authority.*

8. The Authority shall—

(a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matters,

(b) publicise the services provided to the public by the Authority or provided in pursuance of licences,

(c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so, and

(d) perform such other functions as may be specified in regulations.

*Licence committees and other committees.*

9.—(1) The Authority shall maintain one or more committees to discharge the Authority's functions relating to the grant, variation, suspension and revocation of licences, and a committee discharging those functions is referred to in this Act as a "licence committee".

(2) The Authority may provide for the discharge of any of its other functions by committees or by members or employees of the Authority.

(3) A committee (other than a licence committee) may appoint sub-committees.

(4) Persons, committees or sub-committees discharging functions of the Authority shall do so in accordance with any general directions of the Authority.

(5) A licence committee shall consist of such number of persons as may be specified in or determined in accordance with regulations, all being members of the Authority, and shall include at least one person who is not authorised to carry on or participate in any activity under the authority of a licence and would not be so authorised if outstanding applications were granted.

(6) A committee (other than a licence committee) or a sub-committee may include a minority of persons who are not members of the Authority.

(7) Subject to subsection (10) below, a licence committee, before considering an application for authority—

(a) for a person to carry on an activity governed by this Act which he is not then authorised to carry on, or

(b) for a person to carry on any such activity on premises where he is not then authorised to carry it on, shall arrange for the premises where the activity is to be carried on to be inspected on its behalf, and for a report on the inspection to be made to it.

(8) Subject to subsection (9) below, a licence committee shall arrange for any premises to which a licence relates to be inspected on its behalf once in each calendar year, and for a report on the inspection to be made to it.

(9) Any particular premises need not be inspected in any particular year if the licence committee considers an inspection in that year unnecessary.

(10) A licence committee need not comply with subsection (7) above where the premises in question have been inspected in pursuance of that subsection or subsection (8) above at some time during the period of one year ending with the date of the application, and the licence committee considers that a further inspection is not necessary.

(11) An inspection in pursuance of subsection (7) or (8) above may be carried out by a person who is not a member of a licence committee.

*Licensing procedure.*

10.—(1) Regulations may make such provision as appears to the Secretary of State to be necessary or desirable about the proceedings of licence committees and of the Authority on any appeal from such a committee.

(2) The regulations may in particular include provision—

- (a) for requiring persons to give evidence or to produce documents, and
- (b) about the admissibility of evidence.

*Scope of licences*

*Licences for treatment, storage and research.*

11.—(1) The Authority may grant the following and no other licences—

- (a) licences under paragraph 1 of Schedule 2 to this Act authorising activities in the course of providing treatment services,
- (b) licences under that Schedule authorising the storage of gametes and embryos, and
- (c) licences under paragraph 3 of that Schedule authorising activities for the purpose of a project of research.

(2) Paragraph 4 of that Schedule has effect in the case of all licences.

*Licence conditions*

*General conditions.*

12. The following shall be conditions of every licence granted under this Act—

- (a) that the activities authorised by the licence shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,
- (b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),
- (c) that the provisions of Schedule 3 to this Act shall be complied with,

- (d) that proper records shall be maintained in such form as the Authority may specify in directions,
- (e) that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions,
- (f) that, where gametes or embryos are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in directions, and
- (g) that the Authority shall be provided, in such form and at such intervals as it may specify in directions, with such copies of or extracts from the records, or such other information, as the directions may specify.

*Conditions of licences for treatment.*

13.—(1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.

(2) Such information shall be recorded as the Authority may specify in directions about the following—

- (a) the persons for whom services are provided in pursuance of the licence,
- (b) the services provided for them,
- (c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
- (d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,
- (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
- (f) such other matters as the Authority may specify in directions.

(3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.

(4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

(5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.

(6) A woman shall not be provided with any treatment services involving—

- (a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to this Act for the use in question,
- (b) the use of any embryo the creation of which was brought about *in vitro*,

or

(c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,

unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been



provided with such relevant information as is proper.

(7) Suitable procedures shall be maintained—

(a) for determining the persons providing gametes or from whom embryos are taken for use in pursuance of the licence, and

(b) for the purpose of securing that consideration is given to the use of practices not requiring the authority of a licence as well as those requiring such authority.

*Conditions of storage licences.*

14.—(1) The following shall be conditions of every licence authorising the storage of gametes or embryos—

(a) that gametes of a person or an embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a licence applies and that an embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence applies,

(b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,

(c) that no gametes or embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish, and

(d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.

(2) No information shall be removed from any record maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.

(3) The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.

(4) The statutory storage period in respect of embryos is such period not exceeding five years as the licence may specify.

(5) Regulations may provide that subsection (3) or (4) above shall have effect as if for ten years or, as the case may be, five years there were substituted—

(a) such shorter period, or

(b) in such circumstances as may be specified in the regulations, such longer period,  
as may be specified in the regulations.

*Conditions of research licences.*

15.—(1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.

(2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.

(3) No information shall be removed from any records maintained in

pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.

(4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

*Grant, revocation and suspension of licences*

*Grant of licence.*

16.—(1) Where application is made to the Authority in a form approved for the purpose by it accompanied by the initial fee, a licence may be granted to any person by a licence committee if the requirements of subsection (2) below are met and any additional fee is paid.

(2) The requirements mentioned in subsection (1) above are—

(a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,

(b) that either that individual is the applicant or—

(i) the application is made with the consent of that individual, and

(ii) the licence committee is satisfied that the applicant is a suitable person to hold a licence,

(c) that the licence committee is satisfied that the character, qualifications and experience of that individual are such as are required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act,

(d) that the licence committee is satisfied that the premises in respect of which the licence is to be granted are suitable for the activities, and

(e) that all the other requirements of this Act in relation to the granting of the licence are satisfied.

(3) The grant of a licence to any person may be by way of renewal of a licence granted to that person, whether on the same or different terms.

(4) Where the licence committee is of the opinion that the information provided in the application is insufficient to enable it to determine the application, it need not consider the application until the applicant has provided it with such further information as it may require him to provide.

(5) The licence committee shall not grant a licence unless a copy of the conditions to be imposed by the licence has been shown to, and acknowledged in writing by, the applicant and (where different) the person under whose supervision the activities are to be carried on.

(6) In subsection (1) above "initial fee" and "additional fee" mean a fee of such amount as may be fixed from time to time by the Authority with the approval of the Secretary of State and the Treasury, and in determining any such amount, the Authority may have regard to the costs of performing all its functions.

(7) Different fees may be fixed for different circumstances and fees paid under this section are not repayable.

*The person responsible.*

17.—(1) It shall be the duty of the individual under whose supervision the

duty under section 17 of this Act, and

(b) the application is made with the consent of the other individual.

(6) Except on an application under subsection (5) above, a licence can only be varied under this section—

(a) so far as it relates to the activities authorised by the licence, the manner in which they are conducted or the conditions of the licence, or

(b) so as to extend or restrict the premises to which the licence relates.

*Procedure for refusal, variation or revocation of licence.*

19.—(1) Where a licence committee proposes to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, the committee shall give notice of the proposal, the reasons for it and the effect of subsection (3) below to the applicant.

(2) Where a licence committee proposes to vary or revoke a licence, the committee shall give notice of the proposal, the reasons for it and the effect of subsection (3) below to the person responsible and the nominal licensee (but not to any person who has applied for the variation or revocation).

(3) If, within the period of twenty-eight days beginning with the day on which notice of the proposal is given, any person to whom notice was given under subsection (1) or (2) above gives notice to the committee of a wish to make to the committee representations about the proposal in any way mentioned in subsection (4) below, the committee shall, before making its determination, give the person an opportunity to make representations in that way.

(4) The representations may be—

(a) oral representations made by the person, or another acting on behalf of the person, at a meeting of the committee, and

(b) written representations made by the person.

(5) A licence committee shall—

(a) in the case of a determination to grant a licence, give notice of the determination to the person responsible and the nominal licensee.

(b) in the case of a determination to refuse a licence, or to refuse to vary a licence so as to designate another individual in place of the person responsible, give such notice to the applicant, and

(c) in the case of a determination to vary or revoke a licence, give such notice to the person responsible and the nominal licensee.

(6) A licence committee giving notice of a determination to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, or of a determination to vary or revoke a licence otherwise than on an application by the person responsible or the nominal licensee, shall give in the notice the reasons for its decision.

*Appeal to Authority against determinations of licence committee.*

20.—(1) Where a licence committee determines to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, the applicant may appeal to the Authority if notice has been given to the committee and to the Authority before the end of the period of twenty-eight days beginning with the date on which notice of the committee's determination was served on the applicant.

duty under section 17 of this Act, and

(b) the application is made with the consent of the other individual.

(6) Except on an application under subsection (5) above, a licence can only be varied under this section—

(a) so far as it relates to the activities authorised by the licence, the manner in which they are conducted or the conditions of the licence, or

(b) so as to extend or restrict the premises to which the licence relates.

*Procedure for refusal, variation or revocation of licence.*

19.—(1) Where a licence committee proposes to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, the committee shall give notice of the proposal, the reasons for it and the effect of subsection (3) below to the applicant.

(2) Where a licence committee proposes to vary or revoke a licence, the committee shall give notice of the proposal, the reasons for it and the effect of subsection (3) below to the person responsible and the nominal licensee (but not to any person who has applied for the variation or revocation).

(3) If, within the period of twenty-eight days beginning with the day on which notice of the proposal is given, any person to whom notice was given under subsection (1) or (2) above gives notice to the committee of a wish to make to the committee representations about the proposal in any way mentioned in subsection (4) below, the committee shall, before making its determination, give the person an opportunity to make representations in that way.

(4) The representations may be—

(a) oral representations made by the person, or another acting on behalf of the person, at a meeting of the committee, and

(b) written representations made by the person.

(5) A licence committee shall—

(a) in the case of a determination to grant a licence, give notice of the determination to the person responsible and the nominal licensee.

(b) in the case of a determination to refuse a licence, or to refuse to vary a licence so as to designate another individual in place of the person responsible, give such notice to the applicant, and

(c) in the case of a determination to vary or revoke a licence, give such notice to the person responsible and the nominal licensee.

(6) A licence committee giving notice of a determination to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, or of a determination to vary or revoke a licence otherwise than on an application by the person responsible or the nominal licensee, shall give in the notice the reasons for its decision.

*Appeal to Authority against determinations of licence committee.*

20.—(1) Where a licence committee determines to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, the applicant may appeal to the Authority if notice has been given to the committee and to the Authority before the end of the period of twenty-eight days beginning with the date on which notice of the committee's determination was served on the applicant.

(2) Where a licence committee determines to vary or revoke a licence, any person on whom notice of the determination was served (other than a person who applied for the variation or revocation) may appeal to the Authority if notice has been given to the committee and to the Authority before the end of the period of twenty-eight days beginning with the date on which notice of the committee's determination was served.

(3) An appeal under this section shall be by way of rehearing by the Authority and no member of the Authority who took any part in the proceedings resulting in the determination appealed against shall take any part in the proceedings on appeal.

(4) On the appeal—

(a) the appellant shall be entitled to appear or be represented,

(b) the members of the licence committee shall be entitled to appear, or the committee shall be entitled to be represented, and

(c) the Authority shall consider any written representations received from the appellant or any member of the committee and may take into account any matter that could be taken into account by a licence committee, and the Authority may make such determination on the appeal as it thinks fit.

(5) The Authority shall give notice of its determination to the appellant and, if it is a determination to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible or a determination to vary or revoke a licence, shall include in the notice the reasons for the decision.

(6) The functions of the Authority on an appeal under this section cannot be discharged by any committee, member or employee of the Authority and, for the purposes of the appeal, the quorum shall not be less than five.

*Appeals to High Court or Court of Session.*

21. Where the Authority determines under section 20 of this Act—

(a) to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, or

(b) to vary or revoke a licence,

any person on whom notice of the determination was served may appeal to the High Court or, in Scotland, the Court of Session on a point of law.

*Temporary suspension of licence.*

22.—(1) Where a licence committee—

(a) has reasonable grounds to suspect that there are grounds for revoking the licence under section 18 of this Act, and

(b) is of the opinion that the licence should immediately be suspended, it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.

(2) Notice under subsection (1) above shall be given to the person responsible or, where the person responsible has died or appears to the licence committee to be unable because of incapacity to discharge the duty under section 17 of this Act, to some other person to whom the licence applies or the nominal licensee and a licence committee may, by a further notice to that person, renew or further renew the notice under subsection (1) above for such further period not exceeding

three months as may be specified in the renewal notice.

(3) While suspended under this section a licence shall be of no effect, but application may be made under section 18(5) of this Act by the nominal licensee to designate another individual as the person responsible.

#### *Directions and guidance*

##### *Directions: general.*

23.—(1) The Authority may from time to time give directions for any purpose for which directions may be given under this Act or directions varying or revoking such directions.

(2) A person to whom any requirement contained in directions is applicable shall comply with the requirement.

(3) Anything done by a person in pursuance of directions is to be treated for the purposes of this Act as done in pursuance of a licence.

(4) Where directions are to be given to a particular person, they shall be given by serving notice of the directions on the person.

(5) In any other case, directions may be given—

(a) in respect of any licence (including a licence which has ceased to have effect), by serving notice of the directions on the person who is or was the person responsible or the nominal licensee, or

(b) if the directions appear to the Authority to be general directions or it appears to the Authority that it is not practicable to give notice in pursuance of paragraph (a) above, by publishing the directions in such way as, in the opinion of the Authority, is likely to bring the directions to the attention of the persons to whom they are applicable.

(6) This section does not apply to directions under section 9(4) of this Act.

##### *Directions as to particular matters.*

24.—(1) If, in the case of any information about persons for whom treatment services were provided, the person responsible does not know that any child was born following the treatment, the period specified in directions by virtue of section 13(4) of this Act shall not expire less than 50 years after the information was first recorded.

(2) In the case of every licence under paragraph 1 of Schedule 2 to this Act, directions shall require information to be recorded and given to the Authority about each of the matters referred to in section 13(2)(a) to (e) of this Act.

(3) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.

(4) Directions may authorise any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

(5) A licence committee may from time to time give such directions as are

mentioned in subsection (7) below where a licence has been varied or has ceased to have effect (whether by expiry, suspension, revocation or otherwise).

(6) A licence committee proposing to suspend, revoke or vary a licence may give such directions as are mentioned in subsection (7) below.

(7) The directions referred to in subsections (5) and (6) above are directions given for the purpose of securing the continued discharge of the duties of the person responsible under the licence concerned ("the old licence"), and such directions may, in particular—

(a) require anything kept or information held in pursuance of the old licence to be transferred to the Authority or any other person, or

(b) provide for the discharge of the duties in question by any individual, being an individual whose character, qualifications and experience are, in the opinion of the committee, such as are required for the supervision of the activities authorised by the old licence, and authorise those activities to be carried on under the supervision of that individual,

but cannot require any individual to discharge any of those duties unless the individual has consented in writing to do so.

(8) Directions for the purpose referred to in subsection (7)(a) above shall be given to the person responsible under the old licence or, where that person has died or appears to the licence committee to have become unable because of incapacity to discharge the duties in question, to some other person to whom the old licence applies or applied or to the nominal licensee.

(9) Directions for the purpose referred to in subsection (7)(b) above shall be given to the individual who under the directions is to discharge the duty.

(10) Where a person who holds a licence dies, anything done subsequently by an individual which that individual would have been authorised to do if the licence had continued in force shall, until directions are given by virtue of this section, be treated as authorised by a licence.

(11) Where the Authority proposes to give directions specifying any animal for the purposes of paragraph 1(1)(f) or 3(5) of Schedule 2 to this Act, it shall report the proposal to the Secretary of State; and the directions shall not be given until the Secretary of State has laid a copy of the report before each House of Parliament.

#### *Code of practice.*

25.—(1) The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.

(2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services (including a child's need for a father), and of other children who may be affected by such births.

(3) The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.

(4) The Authority may from time to time revise the whole or any part of the code.

- (5) The Authority shall publish the code as for the time being in force.
- (6) A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but—
  - (a) a licence committee shall, in considering whether there has been any failure to comply with any conditions of a licence and, in particular, conditions requiring anything to be "proper" or "suitable", take account of any relevant provision of the code, and
  - (b) a licence committee may, in considering, where it has power to do so, whether or not to vary or revoke a licence, take into account any observance of or failure to observe the provisions of the code.

*Procedure for approval of code.*

26.—(1) The Authority shall send a draft of the proposed first code of practice under section 25 of this Act to the Secretary of State within twelve months of the commencement of section 5 of this Act.

(2) If the Authority proposes to revise the code or, if the Secretary of State does not approve a draft of the proposed first code, to submit a further draft, the Authority shall send a draft of the revised code or, as the case may be, a further draft of the proposed first code to the Secretary of State.

(3) Before preparing any draft, the Authority shall consult such persons as the Secretary of State may require it to consult and such other persons (if any) as it considers appropriate.

(4) If the Secretary of State approves a draft, he shall lay it before Parliament and, if he does not approve it, he shall give reasons to the Authority.

(5) A draft approved by the Secretary of State shall come into force in accordance with directions.

*Status*

*Meaning of "mother".*

27.—(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.

(2) Subsection (1) above does not apply to any child to the extent that the child is treated by virtue of adoption as not being the child of any person other than the adopter or adopters.

(3) Subsection (1) above applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

*Meaning of "father".*

28.—(1) This section applies in the case of a child who is being or has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination.

(2) If—

(a) at the time of the placing in her of the embryo or the sperm and eggs or of her insemination, the woman was a party to a marriage, and

(b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage,



then, subject to subsection (5) below, the other party to the marriage shall be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her insemination (as the case may be).

(3) If no man is treated, by virtue of subsection (2) above, as the father of the child but—

(a) the embryo or the sperm and eggs were placed in the woman, or she was artificially inseminated, in the course of treatment services provided for her and a man together by a person to whom a licence applies, and

(b) the creation of the embryo carried by her was not brought about with the sperm of that man,

then, subject to subsection (5) below, that man shall be treated as the father of the child.

(4) Where a person is treated as the father of the child by virtue of subsection (2) or (3) above, no other person is to be treated as the father of the child.

(5) Subsections (2) and (3) above do not apply—

(a) in relation to England and Wales and Northern Ireland, to any child who, by virtue of the rules of common law, is treated as the legitimate child of the parties to a marriage,

(b) in relation to Scotland, to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage, or

(c) to any child to the extent that the child is treated by virtue of adoption as not being the child of any person other than the adopter or adopters.

(6) Where—

(a) the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to this Act was used for a purpose for which such consent was required, or

(b) the sperm of a man, or any embryo the creation of which was brought about with his sperm, was used after his death,

he is not to be treated as the father of the child.

(7) The references in subsection (2) above to the parties to a marriage at the time there referred to—

(a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but

(b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of this subsection it shall be presumed, unless the contrary is shown, that one of them reasonably believed at the time that the marriage was valid.

(8) This section applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(9) In subsection (7)(a) above, "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

*Effect of sections 27 and 28.*

29.—(1) Where by virtue of section 27 or 28 of this Act a person is to be treated

as the mother or father of a child, that person is to be treated in law as the mother or, as the case may be, father of the child for all purposes.

(2) Where by virtue of section 27 or 28 of this Act a person is not to be treated as the mother or father of a child, that person is to be treated in law as not being the mother or, as the case may be, father of the child for any purpose.

(3) Where subsection (1) or (2) above has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.

(4) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 27(1) or 28(2) to (4), read with this section, affects—

(a) the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or

(b) the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.

(5) In relation to Scotland—

(a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of the holder thereof or affect the succession thereto or the devolution thereof, and

(b) where the terms of any deed provide that any property or interest in property shall devolve along with a title, coat of arms, honour or dignity, nothing in those provisions shall prevent that property or interest from so devolving.

*Parental orders in favour of gamete donors.*

30.—(1) The court may make an order providing for a child to be treated in law as the child of the parties to a marriage (referred to in this section as “the husband” and “the wife”) if—

(a) the child has been carried by a woman other than the wife as the result of the placing in her of an embryo or sperm and eggs or her artificial insemination,

(b) the gametes of the husband or the wife, or both, were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to (7) below are satisfied.

(2) The husband and the wife must apply for the order within six months of the birth of the child or, in the case of a child born before the coming into force of this Act, within six months of such coming into force.

(3) At the time of the application and of the making of the order—

(a) the child's home must be with the husband and the wife, and

(b) the husband or the wife, or both of them, must be domiciled in a part of the United Kingdom or in the Channel Islands or the Isle of Man.

(4) At the time of the making of the order both the husband and the wife must have attained the age of eighteen.

(5) The court must be satisfied that both the father of the child (including a person who is the father by virtue of section 28 of this Act), where he is not the husband, and the woman who carried the child have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(6) Subsection (5) above does not require the agreement of a person who cannot be found or is incapable of giving agreement and the agreement of the woman who carried the child is ineffective for the purposes of that subsection if given by her less than six weeks after the child's birth.

(7) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by the husband or the wife for or in consideration of—

- (a) the making of the order,
  - (b) any agreement required by subsection (5) above,
  - (c) the handing over of the child to the husband and the wife, or
  - (d) the making of any arrangements with a view to the making of the order,
- unless authorised by the court.

(8) For the purposes of an application under this section—

(a) in relation to England and Wales, section 92(7) to (10) of, and Part I of Schedule 11 to, the Children Act 1989 (jurisdiction of courts) shall apply for the purposes of this section to determine the meaning of "the court" as they apply for the purposes of that Act and proceedings on the application shall be "family proceedings" for the purposes of that Act,

(b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.

(9) Regulations may provide—

(a) for any provision of the enactments about adoption to have effect, with such modifications (if any) as may be specified in the regulations, in relation to orders under this section, and applications for such orders, as it has effect in relation to adoption, and applications for adoption orders, and

(b) for references in any enactment to adoption, an adopted child or an adoptive relationship to be read (respectively) as references to the effect of an order under this section, a child to whom such an order applies and a relationship arising by virtue of the enactments about adoption, as applied by the regulations, and for similar expressions in connection with adoption to be read accordingly, and the regulations may include such incidental or supplemental provision as appears to the Secretary of State necessary or desirable in consequence of any provision made by virtue of paragraph (a) or (b) above.

(10) In this section "the enactments about adoption" means the Adoption Act 1976, the Adoption (Scotland) Act 1978 and the Adoption (Northern Ireland) Order 1987.

(11) Subsection (1)(a) above applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

### *Information*

*The Authority's register of information.*

31.—(1) The Authority shall keep a register which shall contain any information obtained by the Authority which falls within subsection (2) below.

- (2) Information falls within this subsection if it relates to—
- (a) the provision of treatment services for any identifiable individual, or
  - (b) the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
- or if it shows that any identifiable individual was, or may have been, born in consequence of treatment services.
- (3) A person who has attained the age of eighteen ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (4) below, and the Authority shall do so if—
- (a) the information contained in the register shows that the applicant was, or may have been, born in consequence of treatment services, and
  - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person other than a parent of the applicant would or might, but for sections 27 to 29 of this Act, be a parent of the applicant and, if it does show that—
- (a) giving the applicant so much of that information as relates to the person concerned as the Authority is required by regulations to give (but no other information), or
  - (b) stating whether or not that information shows that, but for sections 27 to 29 of this Act, the applicant, and a person specified in the request as a person whom the applicant proposes to marry, would or might be related.
- (5) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question.
- (6) A person who has not attained the age of eighteen ("the minor") may by notice to the Authority specifying another person ("the intended spouse") as a person whom the minor proposes to marry require the Authority to comply with a request under subsection (7) below, and the Authority shall do so if—
- (a) the information contained in the register shows that the minor was, or may have been, born in consequence of treatment services, and
  - (b) the minor has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (7) The minor may request the Authority to give the minor notice stating whether or not the information contained in the register shows that, but for sections 27 to 29 of this Act, the minor and the intended spouse would or might be related.

*Information to be provided to Registrar General.*

32.—(1) This section applies where a claim is made before the Registrar General that a man is or is not the father of a child and it is necessary or desirable for the purpose of any function of the Registrar General to determine whether the claim is or may be well-founded.

- (2) The Authority shall comply with any request made by the Registrar

General by notice to the Authority to disclose whether any information on the register kept in pursuance of section 31 of this Act tends to show that the man may be the father of the child by virtue of section 28 of this Act and, if it does, disclose that information.

(3) In this section and section 33 of this Act, "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or the Registrar General for Northern Ireland, as the case may be.

*Restrictions on disclosure of information.*

33.—(1) No person who is or has been a member or employee of the Authority shall disclose any information mentioned in subsection (2) below which he holds or has held as such a member or employee.

(2) The information referred to in subsection (1) above is—

(a) any information contained or required to be contained in the register kept in pursuance of section 31 of this Act, and

(b) any other information obtained by any member or employee of the Authority on terms or in circumstances requiring it to be held in confidence.

(3) Subsection (1) above does not apply to any disclosure of information mentioned in subsection (2)(a) above made—

(a) to a person as a member or employee of the Authority,

(b) to a person to whom a licence applies for the purposes of his functions as such,

(c) so that no individual to whom the information relates can be identified,

(d) in pursuance of an order of a court under section 34 or 35 of this Act,

(e) to the Registrar General in pursuance of a request under section 32 of this Act, or

(f) in accordance with section 31 of this Act.

(4) Subsection (1) above does not apply to any disclosure of information mentioned in subsection (2)(b) above—

(a) made to a person as a member or employee of the Authority,

(b) made with the consent of the person or persons whose confidence would otherwise be protected, or

(c) which has been lawfully made available to the public before the disclosure is made.

(5) No person who is or has been a person to whom a licence applies and no person to whom directions have been given shall disclose any information falling within section 31(2) of this Act which he holds or has held as such a person.

(6) Subsection (5) above does not apply to any disclosure of information made—

(a) to a person as a member or employee of the Authority,

(b) to a person to whom a licence applies for the purposes of his functions as such,

(c) so far as it identifies a person who, but for sections 27 to 29 of this Act, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, but only for the purpose of defending such proceedings, or instituting connected proceedings for

compensation against that parent,

(d) so that no individual to whom the information relates can be identified.

or

(e) in pursuance of directions given by virtue of section 24(5) or (6) of this Act.

(7) This section does not apply to the disclosure to any individual of information which—

(a) falls within section 31(2) of this Act by virtue of paragraph (a) or (b) of that subsection, and

(b) relates only to that individual or, in the case of an individual treated together with another, only to that individual and that other.

(8) At the end of Part IV of the Data Protection Act 1984 (Exemptions) there is inserted—

*"Information about human embryos, etc.*

35A. Personal data consisting of information showing that an identifiable individual was, or may have been born in consequence of treatment services (within the meaning of the Human Fertilisation and Embryology Act 1990) are exempt from the subject access provisions except so far as their disclosure under those provisions is made in accordance with section 31 of that Act (the Authority's register of information)."

*Disclosure in interests of justice.*

34.—(1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority—

(a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and

(b) if it is, to disclose so much of it as is specified in the order, but such an order may not require the Authority to disclose any information falling within section 31(2)(b) of this Act.

(2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account—

(a) any representations made by any individual who may be affected by the disclosure, and

(b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.

(3) If the proceedings before the court are civil proceedings, it—

(a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and

(b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.

(4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

*Disclosure in interests of justice: congenital disabilities, etc.*

35.—(1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born

disabled) it is necessary to identify a person who would or might be the parent of a child but for sections 27 to 29 of this Act, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for sections 27 to 29 of this Act, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(3) Subsections (2) to (4) of section 34 of this Act apply for the purposes of this section as they apply for the purposes of that.

(4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted—

“(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990.”.

### *Surrogacy*

#### *Amendment of Surrogacy Arrangements Act 1985.*

36.—(1) After section 1 of the Surrogacy Arrangements Act 1985 there is inserted—

“*Surrogacy arrangements unenforceable.*

1A. No surrogacy arrangement is enforceable by or against any of the persons making it.”

(2) In section 1 of that Act (meaning of “surrogate mother”, etc.)—

(a) in subsection (6), for “or, as the case may be, embryo insertion” there is substituted “or of the placing in her of an embryo, of an egg in the process of fertilisation or of sperm and eggs, as the case may be,” and

(b) in subsection (9), the words from “and whether” to the end are repealed.

### *Abortion*

#### *Amendment of law relating to termination of pregnancy.*

37.—(1) For paragraphs (a) and (b) of section 1(1) of the Abortion Act 1967 (grounds for medical termination of pregnancy) there is substituted—

“(a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family; or

- (b) that the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman; or
- (c) that the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated; or
- (d) that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped."
- (2) In section 1(2) of that Act, after "(a)" there is inserted "or (b)".
- (3) After section 1(3) of that Act there is inserted—  
 "(3A) The power under subsection (3) of this section to approve a place includes power, in relation to treatment consisting primarily in the use of such medicines as may be specified in the approval and carried out in such manner as may be so specified, to approve a class of places."
- (4) For section 5(1) of that Act (effect on Infant Life (Preservation) Act 1929) there is substituted—  
 "(1) No offence under the Infant Life (Preservation) Act 1929 shall be committed by a registered medical practitioner who terminates a pregnancy in accordance with the provisions of this Act."
- (5) In section 5(2) of that Act, for the words from "the miscarriage" to the end there is substituted "a woman's miscarriage (or, in the case of a woman carrying more than one foetus, her miscarriage of any foetus) is unlawfully done unless authorised by section 1 of this Act and, in the case of a woman carrying more than one foetus, anything done with intent to procure her miscarriage of any foetus is authorised by that section if—  
 (a) the ground for termination of the pregnancy specified in subsection (1)(d) of that section applies in relation to any foetus and the thing is done for the purpose of procuring the miscarriage of that foetus, or  
 (b) any of the other grounds for termination of the pregnancy specified in that section applies".

### *Conscientious objection*

#### *Conscientious objection.*

- 38.—**(1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.
- (2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.
- (3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

### *Enforcement*

#### *Powers of members and employees of Authority.*

- 39.—**(1) Any member or employee of the Authority entering and inspecting premises to which a licence relates may—



(a) take possession of anything which he has reasonable grounds to believe may be required—

(i) for the purpose of the functions of the Authority relating to the grant, variation, suspension and revocation of licences, or

(ii) for the purpose of being used in evidence in any proceedings for an offence under this Act,

and retain it for so long as it may be required for the purpose in question, and

(b) for the purpose in question, take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.

(2) In subsection (1) above—

(a) the references to things include information recorded in any form, and

(b) the reference to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the information in legible form and taking possession of the copy.

(3) Nothing in this Act makes it unlawful for a member or employee of the Authority to keep any embryo or gametes in pursuance of that person's functions as such.

*Power to enter premises.*

**40.—(1)** A justice of the peace (including, in Scotland, a sheriff) may issue a warrant under this section if satisfied by the evidence on oath of a member or employee of the Authority that there are reasonable grounds for suspecting that an offence under this Act is being, or has been, committed on any premises.

(2) A warrant under this section shall authorise any named member or employee of the Authority (who must, if so required, produce a document identifying himself), together with any constables—

(a) to enter the premises specified in the warrant, using such force as is reasonably necessary for the purpose, and

(b) to search the premises and—

(i) take possession of anything which he has reasonable grounds to believe may be required to be used in evidence in any proceedings for an offence under this Act, or

(ii) take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.

(3) A warrant under this section shall continue in force until the end of the period of one month beginning with the day on which it is issued.

(4) Anything of which possession is taken under this section may be retained—

(a) for a period of six months, or

(b) if within that period proceedings to which the thing is relevant are commenced against any person for an offence under this Act, until the conclusion of those proceedings.

## (5) In this section—

- (a) the references to things include information recorded in any form, and
- (b) the reference in subsection (2)(b)(i) above to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the information in legible form and taking possession of the copy.

*Offences**Offences.*

## 41.—(1) A person who—

- (a) contravenes section 3(2) or 4(1)(c) of this Act, or
  - (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,
- is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

## (2) A person who—

- (a) contravenes section 3(1) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,
  - (b) keeps or uses any gametes in contravention of section 4(1)(a) or (b) of this Act,
  - (c) contravenes section 4(3) of this Act, or
  - (d) fails to comply with any directions given by virtue of section 24(7)(a) of this Act,
- is guilty of an offence.

## (3) If a person—

- (a) provides any information for the purposes of the grant of a licence, being information which is false or misleading in a material particular, and
  - (b) either he knows the information to be false or misleading in a material particular or he provides the information recklessly,
- he is guilty of an offence.

## (4) A person guilty of an offence under subsection (2) or (3) above is liable—

- (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and
- (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

## (5) A person who discloses any information in contravention of section 33 of this Act is guilty of an offence and liable—

- (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and
- (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

## (6) A person who—

- (a) fails to comply with a requirement made by virtue of section 39(1)(b) or (2)(b) or 40(2)(b)(ii) or (5)(b) of this Act, or
- (b) intentionally obstructs the exercise of any rights conferred by a warrant issued under section 40 of this Act,

is guilty of an offence.

(7) A person who without reasonable excuse fails to comply with a requirement imposed by regulations made by virtue of section 10(2)(a) of this Act is guilty of an offence.

(8) Where a person to whom a licence applies or the nominal licensee gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes or embryos, he is guilty of an offence.

(9) A person guilty of an offence under subsection (6), (7) or (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

(10) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1) or 4(1) of this Act, cannot be done except in pursuance of a licence to prove—

(a) that the defendant was acting under the direction of another, and

(b) that the defendant believed on reasonable grounds—

(i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, or a person to whom directions had been given by virtue of section 24(9) of this Act, and

(ii) that the defendant was authorised by virtue of the licence or directions to do the thing in question.

(11) It is a defence for a person charged with an offence under this Act to prove—

(a) that at the material time he was a person to whom a licence applied or to whom directions had been given, and

(b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.

#### *Consent to prosecution.*

42. No proceedings for an offence under this Act shall be instituted—

(a) in England and Wales, except by or with the consent of the Director of Public Prosecutions, and

(b) in Northern Ireland, except by or with the consent of the Director of Public Prosecutions for Northern Ireland.

#### *Miscellaneous and General*

##### *Keeping and examining gametes and embryos in connection with crime, etc.*

43.—(1) Regulations may provide—

(a) for the keeping and examination of gametes or embryos, in such manner and on such conditions (if any) as may be specified in regulations, in connection with the investigation of, or proceedings for, an offence (wherever committed), or

(b) for the storage of gametes, in such manner and on such conditions (if any) as may be specified in regulations, where they are to be used only for such purposes, other than treatment services, as may be specified in regulations.

(2) Nothing in this Act makes unlawful the keeping or examination of any gametes or embryos in pursuance of regulations made by virtue of this section.

- (3) In this section "examination" includes use for the purposes of any test.

*Civil liability to child with disability.*

44.—(1) After section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) there is inserted—

*"Extension of section 1 to cover infertility treatments.*

1A.—(1) In any case where—

(a) a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled,

(b) the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of the embryo carried by her or of the gametes used to bring about the creation of the embryo, and

(c) a person is under this section answerable to the child in respect of the act or omission,  
the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child.

(2) Subject to subsection (3) below and the applied provisions of section 1 of this Act, a person (here referred to as "the defendant") is answerable to the child if he was liable in tort to one or both of the parents (here referred to as "the parent or parents concerned") or would, if sued in due time, have been so; and it is no answer that there could not have been such liability because the parent or parents concerned suffered no actionable injury, if there was a breach of legal duty which, accompanied by injury, would have given rise to the liability.

(3) The defendant is not under this section answerable to the child if at the time the embryo, or the sperm and eggs, are placed in the woman or the time of her insemination (as the case may be) either or both of the parents knew the risk of their child being born disabled (that is to say, the particular risk created by the act or omission).

(4) Subsections (5) to (7) of section 1 of this Act apply for the purposes of this section as they apply for the purposes of that but as if references to the parent or the parent affected were references to the parent or parents concerned."

- (2) In section 4 of that Act (interpretation, etc)—

(a) at the end of subsection (2) there is inserted—

"and references to embryos shall be construed in accordance with section 1 of the Human Fertilisation and Embryology Act 1990",

(b) in subsection (3), after "section 1" there is inserted "1A", and

(c) in subsection (4), for "either" there is substituted "any".

*Regulations.*

45.—(1) The Secretary of State may make regulations for any purpose for which regulations may be made under this Act.

(2) The power to make regulations shall be exercisable by statutory instrument.

(3) Regulations may make different provision for different cases.

(4) The Secretary of State shall not make regulations by virtue of section 3(3)(c), 4(2) or (3), 30, 31(4)(a), or 43 of this Act or paragraph 1(1)(g) or 3 of Schedule 2 to this Act unless a draft has been laid before and approved by resolution of each House of Parliament.

(5) A statutory instrument containing regulations shall, if made without a draft having been approved by resolution of each House of Parliament, be subject to annulment in pursuance of a resolution of either House of Parliament.

(6) In this Act "regulations" means regulations under this section.

*Notices.*

**46.—**(1) This section has effect in relation to any notice required or authorised by this Act to be given to or served on any person.

(2) The notice may be given to or served on the person—

- (a) by delivering it to the person,
- (b) by leaving it at the person's proper address, or
- (c) by sending it by post to the person at that address.

(3) The notice may—

(a) in the case of a body corporate, be given to or served on the secretary or clerk of the body,

(b) in the case of a partnership, be given to or served on any partner, and

(c) in the case of an unincorporated association other than a partnership, be given to or served on any member of the governing body of the association.

(4) For the purposes of this section and section 7 of the Interpretation Act 1978 (service of documents by post) in its application to this section, the proper address of any person is the person's last known address and also—

(a) in the case of a body corporate, its secretary or its clerk, the address of its registered or principal office, and

(b) in the case of an unincorporated association or a member of its governing body, its principal office.

(5) Where a person has notified the Authority of an address or a new address at which notices may be given to or served on him under this Act, that address shall also be his proper address for the purposes mentioned in subsection (4) above or, as the case may be, his proper address for those purposes in substitution for that previously notified.

**47.** The expressions listed in the left-hand column below are respectively defined or (as the case may be) are to be interpreted in accordance with the provisions of this Act listed in the right-hand column in relation to those expressions.

<i>Expression</i>	<i>Relevant provision</i>
Activities governed by this Act	Section 4(5)
Authority	Section 2(1)
Carry, in relation to a child	Section 2(3)
Directions	Section 2(1)
Embryo	Section 1

<i>Expression</i>	<i>Relevant provision</i>
Gametes, eggs or sperm	Section 1
Keeping, in relation to embryos or gametes	Section 2(2)
Licence	Section 2(1)
Licence committee	Section 9(1)
Nominal licensee	Section 17(3)
Person responsible	Section 17(1)
Person to whom a licence applies	Section 17(2)
Statutory storage period	Section 14(3) to (5)
Store, and similar expressions, in relation to embryos or gametes	Section 2(2)
Treatment services	Section 2(1)

*Northern Ireland.*

48.—(1) This Act (except section 37) extends to Northern Ireland.

(2) Subject to any Order made after the passing of this Act by virtue of subsection (1)(a) of section 3 of the Northern Ireland Constitution Act 1973, the activities governed by this Act shall not be transferred matters for the purposes of that Act, but shall for the purposes of subsection (2) of that section be treated as specified in Schedule 3 to that Act.

*Short title, commencement, etc.*

49.—(1) This Act may be cited as the Human Fertilisation and Embryology Act 1990.

(2) This Act shall come into force on such day as the Secretary of State may by order made by statutory instrument appoint and different days may be appointed for different provisions and for different purposes.

(3) Section 27 to 29 of this Act shall have effect only in relation to children carried by women as a result of the placing in them of embryos or of sperm and eggs, or of their artificial insemination (as the case may be), after the commencement of those sections.

(4) Section 27 of the Family Law Reform Act 1987 (artificial insemination) does not have effect in relation to children carried by women as the result of their artificial insemination after the commencement of sections 27 to 29 of this Act.

(5) Schedule 4 to this Act (which makes minor and consequential amendments) shall have effect.

(6) An order under this section may make such transitional provision as the Secretary of State considers necessary or desirable and, in particular, may provide that where activities are carried on under the supervision of a particular individual, being activities which are carried on under the supervision of that individual at the commencement of sections 3 and 4 of this Act, those activities are to be treated, during such period as may be specified in or determined in accordance with the order, as authorised by a licence (having, in addition to the conditions required by this Act, such conditions as may be so specified or determined) under which that individual is the person responsible.

(7) Her Majesty may by Order in Council direct that any of the provisions of this Act shall extend, with such exceptions, adaptations and modifications (if any) as may be specified in the Order, to any of the Channel Islands.

## SCHEDULES

### Section 5. SCHEDULE 1 THE AUTHORITY: SUPPLEMENTARY PROVISIONS

#### *Status and capacity*

1. The Authority shall not be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown; and its property shall not be regarded as property of, or property held on behalf of, the Crown.

2. The Authority shall have power to do anything which is calculated to facilitate the discharge of its functions, or is incidental or conducive to their discharge, except the power to borrow money.

#### *Expenses*

3. The Secretary of State may, with the consent of the Treasury, pay the Authority out of money provided by Parliament such sums as he thinks fit towards its expenses.

#### *Appointment of members*

4—(1) All the members of the Authority (including the chairman and deputy chairman who shall be appointed as such) shall be appointed by the Secretary of State.

(2) In making appointments the Secretary of State shall have regard to the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women.

(3) The following persons are disqualified from being appointed as chairman or deputy chairman of the Authority—

(a) any person who is, or has been, a medical practitioner registered under the Medical Act 1983 (whether fully, provisionally or with limited registration), or under any repealed enactment from which a provision of that Act is derived,

(b) any person who is, or has been, concerned with keeping or using gametes or embryos outside the body, and

(c) any person who is, or has been, directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so.

(4) The Secretary of State shall secure that at least one-third but fewer than half of the other members of the Authority fall within sub-paragraph (3)(a), (b) or (c) above, and that at least one member falls within each of paragraphs (a) and (b).

#### *Tenure of office*

5.—(1) Subject to the following provisions of this paragraph, a person shall hold and vacate office as a member of the Authority in accordance with the terms of his appointment.

(2) A person shall not be appointed as a member of the Authority for more than three years at a time.

(3) A member may at any time resign his office by giving notice to the Secretary of State.

(4) A person who ceases to be a member of the Authority shall be eligible for re-appointment (whether or not in the same capacity).

(5) If the Secretary of State is satisfied that a member of the Authority—

(a) has been absent from meetings of the Authority for six consecutive months or longer without the permission of the Authority, or

(b) has become bankrupt or made an arrangement with his creditors, or, in Scotland, has had his estate sequestrated or has granted a trust deed for or entered into an arrangement with his creditors, or

(c) is unable or unfit to discharge the functions of a member, the Secretary of State may declare his office as a member of the Authority vacant, and notify the declaration in such manner as he thinks fit; and thereupon the office shall become vacant.

*Disqualification of members of Authority for House of Commons and Northern Ireland Assembly*

6. In Part II of Schedule 1 to the House of Commons Disqualification Act 1975 and in Part II of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (bodies of which all members are disqualified) the following entry shall be inserted at the appropriate place in alphabetical order—  
“The Human Fertilisation and Embryology Authority”.

*Remuneration and pensions of members*

7.—(1) The Authority may—

(a) pay to the chairman such remuneration, and

(b) pay or make provision for paying to or in respect of the chairman or any other member such pensions, allowances, fees, expenses or gratuities, as the Secretary of State may, with the approval of the Treasury, determine.

(2) Where a person ceases to be a member of the Authority otherwise than on the expiry of his term of office and it appears to the Secretary of State that there are special circumstances which make it right for him to receive compensation, the Authority may make to him a payment of such amount as the Secretary of State may, with the consent of the Treasury, determine.

*Staff*

8.—(1) The Authority may appoint such employees as it thinks fit, upon such terms and conditions as the Authority, with the approval of the Secretary of State and the consent of the Treasury, may determine.

(2) The Authority shall secure that any employee whose function is, or whose functions include, the inspection of premises is of such character, and is so qualified by training and experience, as to be a suitable person to perform that function.



(3) The Authority shall, as regards such of its employees as with the approval of the Secretary of State it may determine, pay to or in respect of them such pensions, allowances or gratuities (including pensions, allowances or gratuities by way of compensation for loss of employment), or provide and maintain for them such pension schemes (whether contributory or not), as may be so determined.

(4) If an employee of the Authority—

(a) is a participant in any pension scheme applicable to that employment, and

(b) becomes a member of the Authority, he may, if the Secretary of State so determines, be treated for the purposes of the pension scheme as if his service as a member of the Authority were service as employee of the Authority, whether or not any benefits are to be payable to or in respect of him by virtue of paragraph 7 above.

#### *Proceedings*

9.—(1) The Authority may regulate its own proceedings, and make such arrangements as it thinks appropriate for the discharge of its functions.

(2) The Authority may pay to the members of any committee or sub-committee such fees and allowances as the Secretary of State may, with the consent of the Treasury, determine.

10.—(1) A member of the Authority who is any way directly or indirectly interested in a licence granted or proposed to be granted by the Authority shall, as soon as possible after the relevant circumstances have come to his knowledge, disclose the nature of his interest to the Authority.

(2) Any disclosure under sub-paragraph (1) above shall be recorded by the Authority.

(3) Except in such circumstances (if any) as may be determined by the Authority under paragraph 9(1) above, the member shall not participate after the disclosure in any deliberation or decision of the Authority or any licence committee with respect to the licence, and if he does so the deliberation or decision shall be of no effect.

11. The validity of any proceedings of the Authority, or of any committee or sub-committee, shall not be affected by any vacancy among the members or by any defect in the appointment of a member.

#### *Instruments*

12. The fixing of the seal of the Authority shall be authenticated by the signature of the chairman or deputy chairman of the Authority or some other member of the Authority authorised by the Authority to act for that purpose.

13. A document purporting to be duly executed under the seal of the Authority, or to be signed on the Authority's behalf, shall be received in evidence and shall be deemed to be so executed or signed unless the contrary is proved.

*Investigation by Parliamentary Commissioner*

14. The Authority shall be subject to investigation by the Parliamentary Commissioner and accordingly, in Schedule 2 to the Parliamentary Commissioner Act 1967 (which lists the authorities subject to investigation under that Act), the following entry shall be inserted at the appropriate place in alphabetical order—

“Human Fertilisation and Embryology Authority”.

Section 11 etc.

**SCHEDULE 2****ACTIVITIES FOR WHICH LICENCES MAY BE GRANTED***Licences for treatment*

1.—(1) A licence under this paragraph may authorise any of the following in the course of providing treatment services—

- (a) bringing about the creation of embryos *in vitro*,
- (b) keeping embryos,
- (c) using gametes,
- (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,
- (e) placing any embryo in a woman,
- (f) mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is complete and, in any event, not later than the two cell stage, and
- (g) such other practices as may be specified in, or determined in accordance with, regulations.

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services.

(4) A licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo.

(5) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

*Licences for storage*

2.—(1) A licence under this paragraph or paragraph 1 or 3 of this Schedule may authorise the storage of gametes or embryos or both.

(2) Subject to the provisions of this Act, a licence authorising such storage may be granted subject to such conditions as may be specified in the licence and may authorise storage in such manner as may be so specified.

(3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

*Licences for research*

3.—(1) A licence under this paragraph may authorise any of the following—  
(a) bringing about the creation of embryos *in vitro*, and  
(b) keeping or using embryos,  
for the purposes of a project of research specified in the licence.

(2) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of—

- (a) promoting advances in the treatment of infertility,
  - (b) increasing knowledge about the causes of congenital disease,
  - (c) increasing knowledge about the causes of miscarriages,
  - (d) developing more effective techniques of contraception, or
  - (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,
- or for such other purposes as may be specified in regulations.

(3) Purposes may only be so specified with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied.

(4) A licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations.

(5) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, not later than the two cell stage.

(6) No licence under this paragraph shall be granted unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research.

(7) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.

(8) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1) or (5) above in such manner as may be so specified.

(9) A licence under this paragraph shall be granted for such period not exceeding three years as may be specified in the licence.

*General*

4.—(1) A licence under this Schedule can only authorise activities to be carried on on premises specified in the licence and under the supervision of an individual designated in the licence.

(2) A licence cannot—

- (a) authorise activities falling within both paragraph 1 and paragraph 3 above,

- (b) apply to more than one project of research,
- (c) authorise activities to be carried on under the supervision of more than one individual, or
- (d) apply to premises in different places.

Section 12 etc.

### SCHEDULE 3 CONSENTS TO USE OF GAMETES OR EMBRYOS

#### *Consent*

1. A consent under this Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn.

2.—(1) A consent to the use of any embryo must specify one or more of the following purposes—

- (a) use in providing treatment services to the person giving consent, or that person and another specified person together,
  - (b) use in providing treatment services to persons not including the person giving consent, or
  - (c) use for the purposes of any project of research,
- and may specify conditions subject to which the embryo may be so used.

(2) A consent to the storage of any gametes or any embryo must—

- (a) specify the maximum period of storage (if less than the statutory storage period), and
  - (b) state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it,
- and may specify conditions subject to which the gametes or embryo may remain in storage.

(3) A consent under this Schedule must provide for such other matters as the Authority may specify in directions.

(4) A consent under this Schedule may apply—

- (a) to the use or storage of a particular embryo, or
  - (b) in the case of a person providing gametes, to the use or storage of any embryo whose creation may be brought about using those gametes,
- and in the paragraph (b) case the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to a particular embryo or particular embryos.

#### *Procedure for giving consent*

3.—(1) Before a person gives consent under this Schedule—

- (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
- (b) he must be provided with such relevant information as is proper.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 below.

*Variation and withdrawal of consent*

4.—(1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes or embryo to which the consent is relevant.

(2) The terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used—

- (a) in providing treatment services, or
- (b) for the purposes of any project of research.

*Use of gametes for treatment of others*

5.—(1) A person's gametes must not be used for the purposes of treatment services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

*In vitro fertilisation and subsequent use of embryo*

6.—(1) A person's gametes must not be used to bring about the creation of any embryo *in vitro* unless there is an effective consent by that person to any embryo the creation of which may be brought about with the use of those gametes being used for one or more of the purposes mentioned in paragraph 2(1) above.

(2) An embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) above of the embryo.

(3) An embryo the creation of which was brought about *in vitro* must not be used for any purpose unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

(4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

*Embryos obtained by lavage, etc.*

7.—(1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(3) This paragraph does not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

*Storage of gametes and embryos*

8.—(1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

(2) An embryo the creation of which was brought about *in vitro* must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

(3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.

## Section 49.

## SCHEDULE 4

## MINOR AND CONSEQUENTIAL AMENDMENTS

*Family Law Reform Act 1969 (c. 46.)*

1. In section 25 of the Family Law Reform Act 1969 (interpretation), at the end of the definition of "excluded" there is added "to section 27 of the Family Law Reform Act 1987 and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

*Social Security Act 1975 (c. 14.)*

2. In section 25(1) of the Social Security Act 1975 (widowed mother's allowance), for the words from "or" after paragraph (b) to the end there is substituted "or

(c) if the woman and her late husband were residing together immediately before the time of his death, the woman is pregnant as the result of being artificially inseminated before that time with the semen of some person other than her husband, or as the result of the placing in her before that time of an embryo, of an egg in the process of fertilisation, or of sperm and eggs."

*Social Security (Northern Ireland) Act 1975 (c. 15.)*

3. In section 25(1) of the Social Security (Northern Ireland) Act 1975 (widowed mother's allowance), at the end there is inserted "or

(c) if the woman and her late husband were residing together immediately before the time of his death, the woman is pregnant as the result of being artificially inseminated before that time with the semen of some person other than her husband, or as the result of the placing in her before that time of an embryo, of an egg in the process of fertilisation, or of sperm and eggs."

*Adoption Act 1976 (c. 36.)*

4. In section 15 of the Adoption Act 1976 (adoption by one person), in subsection (3)(a) (conditions for making an adoption order on application of one

parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".

*Family Law Reform (Northern Ireland) Order 1977 (S.I. 1977/1250 (N.I. 17))*

5. In Article 13 of the Family Law Reform (Northern Ireland) Order 1977 (interpretation), at the end of the definition of "excluded" there is added "and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

*Adoption (Scotland) Act 1978 (c. 28.)*

6. In section 15 of the Adoption (Scotland) Act 1978 (adoption by one person), in subsection (3)(a) (conditions for making an adoption order on application of one parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".

*Adoption (Northern Ireland) Order 1987 (S.I. 1987/2203 (N.I. 22))*

7. In Article 15 of the Adoption (Northern Ireland) Order 1987 (adoption by one person), in paragraph (3)(a) (conditions for making an adoption order on the application of one parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".

*Human Organ Transplants Act 1989 (c. 31.)*

8. Sections 27 to 29 of this Act do not apply for the purposes of section 2 of the Human Organ Transplants Act 1989 (restrictions on transplants between persons not genetically related).

*Human Organ Transplants (Northern Ireland) Order 1989  
(S.I. 1989/2408 (N.I. 21))*

9. Sections 27 to 29 of this Act do not apply for the purposes of Article 4 of the Human Organ Transplants (Northern Ireland) Order 1989 (restrictions on transplants between persons not genetically related).

## ORGANIZATIONAL STATEMENTS ON EMBRYO RESEARCH

by Lori B. Andrews

The issue of embryo research is of widespread interest. Not only have the governments of individual states and nations taken positions on the subject through legislation, but various medical, legal, and political entities have addressed the issue as well. Among these groups are the American College of Obstetricians and Gynecologists (ACOG),<sup>1</sup> American Fertility Society (AFS),<sup>2</sup> the American Medical Association (AMA),<sup>3</sup> the College of American Pathologists (ACP),<sup>4</sup> the Council of Europe,<sup>5</sup> the European Parliament,<sup>6</sup> the International Law Association (ILA),<sup>7</sup> and the World Medical Association (WMA).<sup>8</sup>

### The Special Status of The Embryo

The organizations that have addressed the issue generally assume that the embryo should be accorded a special status and treated differently than other human tissue. The organizations describe that status in diverse ways. The American Fertility Society, for example, says that the "pre-embryo deserves special respect." The International Law Association describes the embryo as a "member of the human family." The World Medical Association urges respect for the embryo "from the beginning of life."

The organizations differ, however, in how they implement this respect. For some organizations, the appropriate level of respect for embryos entails a prohibition on all research.<sup>9</sup> For others, it means that embryo research must be subject to



particular guidelines regarding its necessity, advance review, limitations on the length of time that the embryo is maintained in a non-cryopreserved state, limitations on implantation of embryos that have been used for research or experimentation, prohibitions on producing embryos for research purposes, and requirements for quality assurance. Some research is specifically favored in particular organization's guidelines. Some guidelines contain prohibitions on certain types of research.

#### **Justification for Research**

Some of the organizational guidelines require that embryo research not be done unless the research has a strong justification. The American Fertility Society, for example, finds that "[r]equests to do research on human pre-embryos should require especially strong justification because of the high moral value accorded to each human embryo."<sup>10</sup> If convincing justification is not provided that would be sufficient cause, according to AFS, to deny approval of a proposed research project.<sup>11</sup>

#### **Advance Review**

The guidelines of the American College of Obstetricians and Gynecologists, the American Fertility Society, the American Medical Association, and Council of Europe provide that proposals for embryo research be reviewed in advance by an Institutional

Review Board (IRB).<sup>12</sup> The American College of Obstetricians and Gynecologists Committee on Ethics recommends that a research protocol clearly describing the design and procedures of the project be submitted to a specially appointed independent committee, to be evaluated, approved and given guidance.<sup>13</sup> The AFS guidelines state that the IRB should seek extramural consultation in order to broaden the moral judgment made. The Council of Europe Parliamentary Assembly resolution invites the member countries to establish regional or national multidisciplinary bodies to authorize specific projects of scientific investigation or experimentation involving human embryos or fetuses.<sup>14</sup>

#### **Length of Time Embryo Could be Maintained in a Non-Cryopreserved State**

Some of the guidelines require that embryos not be maintained in a non-cryopreserved state beyond 14 days of fertilization. The AFS, for example, imposes this restriction.<sup>15</sup> The AFS acknowledges that this time limitation is arbitrary, but it recognizes that individuality and anatomic differentiation of the embryo begin after this time.<sup>16</sup> In addition, one of the principles asserted by the Council of Europe's ad hoc Committee of Experts on Bioethics (CAHBI) is that when a country allows investigative or experimental procedures on embryos for reasons other than prevention, diagnosis or therapy for serious diseases, such research must occur before fourteen days after fertilization

(excluding any period of storage or freezing).<sup>17</sup>

### **Implantation Issues**

One of the principles articulated by CAHBI, the ad hoc Committee of the Council of Europe, prohibits implanting embryos used for research in a woman unless the research was done to diagnose a serious illness or anomaly in or provide therapy for the embryo.<sup>18</sup> The AMA prohibits laboratory research on an embryo that will be implanted in a woman.<sup>19</sup> ACOG recommends that embryos used for research should only be transferred to a woman's uterus if the research was related to preparing the embryo for placement and there is scientific confidence that the embryo will develop normally.<sup>20</sup>

### **Quality Assurance Measures**

Some of the organizational guidelines require adherence to quality assurance mechanisms regarding the laboratory and personnel involved in research activities. The American College of Obstetricians and Gynecologists' guidelines require that researchers be qualified and that the research setting be appropriate with sufficient protections and resources.<sup>21</sup> The guidelines do not specify what protections and resources are adequate. The College of American Pathologists recognizes quality assurance as "the means by which the laboratory director can pursue excellence."<sup>22</sup> To accomplish this, it is recommended that the laboratory design quality control and quality assurance

procedures and rigorously train the staff.<sup>23</sup> In addition, World Medical Association asserts that the physician engaging in an elective procedure such as in vitro fertilization or embryo transfer, "must have adequate specialized training before undertaking the responsibility of performing the procedure."<sup>24</sup>

### **Production of Embryo for Research Purposes**

The organizations vary in whether they would allow the production of embryos for research purposes. The International Law Association<sup>25</sup> and the European Parliament implicitly prohibit the practice.<sup>26</sup> The Council of Europe Parliamentary Assembly explicitly prohibits the practice.<sup>27</sup> The AFS guidelines, on the other hand, allow it. The AFS guidelines point out the disadvantages of limiting research only to excess embryos. Such embryos "may not be a representative sample, which could adversely affect the reliability of the data obtained."<sup>28</sup> In addition, the AFS guidelines suggest that certain studies "may require production of human pre-embryos as an integral part of the analysis, for example, of gamete quality or of the fertilization process itself."<sup>29</sup> The AFS guidelines caution, though, that the obtaining of embryos for basic research should not be done in a manner that puts the donor at significant risk.<sup>30</sup>

### **Favored Research**

Some organizational guidelines provide examples of research

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### **Favored Research**

Some organizational guidelines provide examples of research

implantation, creation of chimeras and creation of hybrids.<sup>38</sup>

### **Rights of Conscience**

The issue of embryo research is sufficiently controversial that some health care providers or researchers may not want to participate in it. The World Medical Association guidelines state that physicians should not violate their own personal moral convictions. Also, one of the principles developed by CAHBI states that:

No person may be compelled or required to take a direct part in the performance of acts mentioned in the present principles to which he/she has an objection on the grounds of conscience.<sup>39</sup>

### **Other Organizational Statements of Interest**

A forthcoming article to be published in the Kennedy Institute Ethics Journal describes several other organizational statements on gene therapy which may be relevant to the issue of embryo research.<sup>40</sup> The article will be published in the March, 1994 issue of the Journal.

### **Organization-by-Organization Descriptions**

The rest of this paper describes in detail the particular approaches taken by each organization.

### American College of Obstetricians and Gynecologists

In 1986 the American College of Obstetricians and Gynecologists Committee on Ethics, issued a committee opinion on Ethical Issues in Human In Vitro Fertilization and Embryo Placement.<sup>41</sup> The guidelines relating to embryo research were designed to "accord... appropriate respect to early human embryos while at the same time allowing the possibility of human embryo research if a convincing rationale for the research can be articulated."<sup>42</sup>

The Committee views the embryo as deserving a higher level of respect than other human cells or tissues because of its potential to become a person.<sup>43</sup> Based on this premise the Committee recommends that laboratory research with early embryos be permitted subject to advance review and be performed utilizing ethical standards.<sup>44</sup> The standards should require that the research project be of such importance to justify the use of embryos;<sup>45</sup> valid scientific conclusions will be derived;<sup>46</sup> the knowledge cannot be gained by using nonhuman embryos;<sup>47</sup> the least amount of embryos possible are to be used<sup>48</sup> and the research is done as early as possible but no later than fourteen days from fertilization.<sup>49</sup>

The Institutional Review Board (IRB) at the facility where the research is to occur should apply these standards.<sup>50</sup> If the project raises serious controversy, the IRB should consider seeking expert consultation.<sup>51</sup>

The guidelines also address the issue of embryo biopsy,

finding the procedure, if demonstrated to be safe and accurate, preferable to prenatal diagnosis and selective abortion during the first two trimesters of pregnancy.<sup>52</sup> The safety of the procedure with regard to potential children needs to be studied.<sup>53</sup>

Recently, ACOG has reconsidered some of these issues in a yet-to-be-published statement on the ethical considerations of pre-embryo research. The Committee distinguishes between pre-embryo and embryo; pre-embryo being that entity which exists after fertilization until approximately 14 days later.<sup>54</sup> The guidelines specifically refer to research at the pre-embryo stage of development. The guidelines do not specifically address the issue of creating pre-embryos solely for research.<sup>55</sup>

The recommendations made in this statement are similar to those articulated in the Committee opinion on Ethical Issues on Human In Vitro Fertilization and Embryo Placement, recognizing the pre-embryo as a living entity deserving of a level of respect.<sup>56</sup> The guidelines require advance review;<sup>57</sup> performance of the research by qualified persons in an appropriate setting;<sup>58</sup> that the purpose of the research cannot be achieved by using animals or nonfertilized gametes;<sup>59</sup> that the information sought may be beneficial with regard to the growth and development of the pre-embryo or embryo;<sup>60</sup> and that the research will be completed at the earliest developmental stage of the pre-embryo (i.e. before 14 days after fertilization).<sup>61</sup>

The ACOG guidelines also contain extensive recommendations



for the informed consent process. Potential donors of gametes must be fully informed of the goals, methods, benefits and risks of the research and that they are free to refuse to participate or withdraw from the research.<sup>62</sup> The ACOG statement attempts to assure that couples make their decisions to participate in research free of coercion. Couples should be assured that donation of pre-embryos for research purposes is not a condition of receiving services and that fee scales are not contingent on making pre-embryos available for research.

The guidelines also recommend that a researched-upon embryo not be implanted unless the research was related to preparing the pre-embryo for implantation and there is reasonable confidence that it will develop normally.<sup>63</sup> Additionally, the research must not involve the sale or purchase of embryos.<sup>64</sup>

#### **American Fertility Society**

In 1986, the Ethics Committee of the American Fertility Society (AFS) issued "Ethical Considerations of the New Reproductive Technologies" which included guidelines applicable to research on human pre-embryos. The purpose of this document is to assist the "involved persons... in the formulation of practical, workable guidelines for both promoting and limiting research on human pre-embryos."<sup>65</sup>

The Committee started from the premise that the "pre-embryo deserves special respect."<sup>66</sup> The AFS guidelines recognize the benefits of research on human pre-embryos provided the research

meets certain criteria. The AFS guidelines state that creation of embryos "may be justifiable in special circumstances."<sup>67</sup> The guidelines do not include any explicit prohibitions of particular activities.

According to the AFS guidelines, basic research on embryos should only be done when no substitute is available and only when data of clinical importance can be obtained.<sup>68</sup> The guidelines provide that embryos should not be maintained for research in the non-cryopreserved state beyond 14 days after fertilization.<sup>69</sup> Research should be reviewed in advance by an Institutional Review Board.<sup>70</sup> Requests to a review board to engage in a particular research protocol "should require especially strong justification because of the high moral value accorded to each human pre-embryo"<sup>71</sup> and, in some circumstances not specified in the guidelines, the Institutional Review Board determining the acceptability of a protocol should seek "extramural consultation in order to broaden the moral judgment to be made."<sup>72</sup>

#### **American Medical Association**

The American Medical Association has several statements of potential relevance to embryo research. The AMA's Council on Ethical and Judicial Affairs described the benefits of embryo research in its ethical opinion on in vitro fertilization. It stated that such research is useful for "an understanding of how genetic defects arise and are transmitted and how they might be prevented or treated."<sup>73</sup>

Consequently the Council concluded that embryo research is permissible<sup>74</sup> so long as the research is conducted in accordance with the Council's guidelines on fetal research and so long as the embryos are not implanted in a woman.<sup>75</sup> The fetal research guidelines<sup>76</sup> require the written voluntary informed consent of the woman and the least possible risk to the fetus. They require that the research be well-defined for the collection of scientifically significant data which cannot be otherwise obtained. They require properly performed previous animal research, and advance review, where appropriate, and prohibit payment to obtain the embryo. In addition, they state that "the investigation should demonstrate the same care and treatment for the [fetus] as a physician providing fetal care or treatment in a non-research setting."<sup>77</sup>

#### **College of American Pathologists**

The College of American Pathologists (ACP) held a conference in 1991 on New Reproductive Biology which resulted in a series of recommendations made by attendants and participants at the Conference. The ACP guidelines provide that "[r]esearch on extra pre-embryos is acceptable ethically and legally."<sup>78</sup> In fact, they suggest that certain types of embryo research are not only acceptable but necessary as well. They assert, for example, that further research using allogenic and xenogenic cells cultured together with embryos is necessary to understand the principles and factors involved in improving the environment for cultured

embryos.<sup>79</sup>

In addition, the ACP guidelines recommend that micromanipulation of embryos "should be further investigated and developed in advanced laboratories that are suitably equipped," since this technique may be important in enhancing fertilization and implantation of embryos.<sup>80</sup> The guidelines also acknowledge that preimplantation embryo biopsy "affords the opportunity for early diagnosis of sex and genetic disease."<sup>81</sup>

The ACP guidelines recognize the importance of quality assurance. One of the recommendations provides that:

[t]he reproductive biology laboratory must design sound quality control and quality assurance procedures to achieve optimal results in semen analysis, sperm function tests, and in vitro fertilization. Training of staff must be rigorous and cannot be achieved without practice or experience and the comparison of results with those of experienced personnel.<sup>82</sup>

### Council of Europe

In February of 1989 the Council of Europe Parliamentary Assembly adopted Recommendation 1100 dealing with the use of human embryos and fetuses in scientific research and with genetic engineering. The purpose of the Recommendation was to "[p]rovide a framework of principles from which national laws or regulations can be developed in as universal and uniform a manner as possible..."<sup>83</sup> The Council supports research on embryos but under limited circumstances.

In its Recommendation, it invites the member country governments to encourage investigations aimed at:

- (a) improving technical procedures of assisted fertilization, strictly as and where permitted;
- (b) deepening knowledge of the human cell and of its structures and its functions, and in particular of reproductive cells, of embryological development, of reproduction and heredity;
- (c) diagnostic (in particular prenatal) and/or therapeutic purposes, especially for diseases linked to chromosomes or genes;
- (d) industrial and pharmacological purposes, so as to produce medically useful substances in sufficient quantities without either the biological disadvantages or risks of infection or immunological reactions caused by the substances usually used.<sup>84</sup>

The Council of Europe's Parliamentary Assembly recommends that member nations establish national or regional multidisciplinary bodies for the purpose of:

informing society and the public authorities of scientific and technological advances in embryology and biological investigations and experimentation, of guiding and monitoring the potential applications thereof, evaluating results, benefits and drawbacks, notably in general terms, that is including also the dimension of human rights, human dignity and other ethical values, and authorizing, provided there are appropriate regulations or delegations of authority, specific projects of scientific investigation or experimentation in these fields.<sup>85</sup>

The Council of Europe's Parliamentary Assembly was also concerned about quality assurance. It recommends that member nations establish registers of accredited or authorized locations where research or experimentation on reproductive material is performed.<sup>86</sup> Additionally, the Parliamentary Assembly recommends that the activities at these centers should be monitored and

evaluated and that the teams engaging in the activities have the appropriate qualities, be authorized to perform the activities and have the necessary resources.<sup>87</sup>

In the appendix to the resolution, permissible and prohibited uses of pre-embryos are described. The Parliamentary Assembly finds that "[t]he intentional creation and/or keeping alive of embryos...for any scientific research purpose...shall be prohibited."<sup>88</sup> Research is prohibited on living embryos when the embryo is viable; an animal model could be used; if not authorized by the appropriate authority; and if not within the time limits established by the authorizing authority.<sup>89</sup> There is a narrow exception to that rule; investigations involving viable preimplantation embryos are only permitted:

- for applied purposes of a diagnostic nature or for preventive or therapeutic purposes;
- if their non-pathological genetic heritage is not interfered with.<sup>90</sup>

Research on dead preimplantation embryos, though, for scientific, diagnostic, therapeutic or other purposes is permissible subject to prior authorization.<sup>91</sup>

The results of all research must be reported back to the authorizing body. Additionally, "[t]he donation and use of human embryological material shall be conditional on the freely given written consent of the donor parents."<sup>92</sup>

In addition to the adoption of these recommendations, the Council's ad hoc Committee of Experts on Progress in Biomedical Sciences (CAHBI) developed an Information Document, "Human

Artificial Procreation."<sup>93</sup> The report is an overview of the work done by CAHBI between 1985 and 1987.<sup>94</sup> Publication of the CAHBI document by the Council of Europe does not imply acceptance of the tenets by the Council of Europe Committee of Ministers.<sup>95</sup> The CAHBI Principles appear to take a more restrictive stance toward research than the approach taken by the Parliamentary Assembly.

The principles define "embryo" as "the result of fusion of human gametes at all stages of development before the fetal stage."<sup>96</sup> CAHBI recommends prohibiting fertilizing ova in vitro and obtaining embryos by lavage for research purposes.<sup>97</sup> Additionally, the group recommends that only therapeutic procedures or harmless observational studies of embryos be permitted.<sup>98</sup> If however, a member country permits other investigative or experimental procedures, CAHBI recommends that the country require that:

- a) the purpose cannot be achieved by any other method; and
- b) the embryo shall not be used after fourteen days from fertilization, any period of storage by freezing or any other means not included; and
- c) the consent of the couple has been given... if the embryo has resulted from fertilization in vitro using donors gametes, their consent shall also be required; and
- d) a properly constituted multidisciplinary ethical committee has given its approval.<sup>99</sup>

Conditions "b", "c" and "d" must be satisfied if the cells of an embryo are to be split for diagnostic purpose or to identify a serious illness in the resulting child's future.<sup>100</sup> In addition,

an embryo subject to investigative or experimental procedures other than for diagnosing a serious illness or anomaly or providing therapy shall not be introduced into a woman's uterus.<sup>101</sup> In order to use an embryo for other than procreative purposes, CAHBI recommends that the consent of both members of the couple be obtained.<sup>102</sup> CAHBI also recommends that "only the minimum number of ova shall be fertilized as is strictly necessary to ensure the success of procreation."<sup>103</sup> No person, though, should be compelled or required to take a direct part in the performance of acts mentioned in the present principles to which he/she has an objection on the grounds of conscience."<sup>104</sup>

CAHBI recommends prohibiting other activities. These activities include utilizing artificial procreation to create identical human beings by cloning or otherwise;<sup>105</sup> cross-species implantation;<sup>106</sup> and fusing human gametes with those of another species, fusing embryos or other procedures to produce chimeras.<sup>107</sup>

Both the Principles enunciated by CAHBI and the Recommendations adopted by the Council of Europe Parliamentary Assembly permit some types of embryo research. Both favor certain activities that arguably benefit the embryo.

### **European Parliament**

In March of 1989, the European Parliament adopted resolutions on genetic engineering and in vitro fertilization which include guidelines on the use of embryos. The European



Parliament "[r]ecognizes the value of life and more especially the human being's rights to protection and therefore expresses its concern at the 'waste' of embryos which in vitro fertilization can entail, [and] hopes that techniques and practices will be employed to eliminate this risk."<sup>108</sup>

Having expressed the view that some level of protection must be afforded to embryos, the European Parliament addresses how this should be accomplished. The European Parliament recommends that only the number of fertilized eggs that can be implanted should be fertilized in vitro;<sup>109</sup> embryos should only be frozen when it is not possible to immediately transfer them into a woman's uterus for reasons occurring at the time of fertilization<sup>110</sup> and storage of frozen embryos should only be permissible if the woman's health temporarily prevents implantation and she states her willingness to have the embryo implanted at a later date.<sup>111</sup> The embryo should be stored for no longer than three years.<sup>112</sup> If it becomes impossible to implant a stored embryo, the embryo is to be taken from storage and "allowed to die."<sup>113</sup> Trade in embryos or experimentation with such embryos should be punishable by law.<sup>114</sup>

The European Parliament appears to be wholly opposed to the creation of embryos in vitro for any reasons other than the therapeutic purpose of relieving infertility.<sup>115</sup> The organization also seems to be opposed to preimplantation diagnosis of embryos. The European Parliament "[i]s convinced that under no circumstances should it be possible to abuse in

vitro fertilization methods to select certain embryos; [and] calls therefore, for a prohibition on any form of genetic experiments on embryos outside the womb."<sup>116</sup>

### International Law Association

At the Sixty-third Conference of the International Law Association held in 1988, the Association adopted a resolution on "reproductive technologies and the protection of the human person." The Conference advocated protection of the embryo as a "member of the human family"<sup>117</sup> and stated that "[n]on-therapeutic research on the human embryo shall be prohibited." Research for therapeutic purposes is subject to the approval of an ethics committee.

Commercialization or trade in embryos is prohibited.<sup>118</sup> The Association also adopted the principle of donors' control over the use of their embryos requiring that "[a]t the time of donation, the donor shall expressly indicate the use of his...embryo(s). The decision of the donor binds the physician and the storage facility."<sup>119</sup> Failure to adhere to any of these principles is to be penalized.<sup>120</sup> Specific penalties are not articulated in the resolution.

The position articulated by the Association is protective of the embryo. It does not forbid all research or experimentation on embryos, but limits such procedures to therapeutic purposes.

## World Medical Association

During the Thirty-ninth World Medical Assembly in 1987, the World Medical Association (WMA) adopted several declarations including a statement on in vitro fertilization and embryo transfer. This statement also addresses the issue of research on embryos.

The statement begins with the WMA encouraging "physicians to act ethically and with appropriate respect for the health of the prospective mother and for the embryo from the beginning of life."<sup>121</sup> Respect for the embryo, however, does not foreclose the acceptability of research. In fact, the WMA recognizes that:

[t]he technique of in vitro fertilization and embryo transplantation can also be useful in research directed towards a better understanding of how genetic defects arise and are transmitted, and how they might be prevented or treated.<sup>122</sup>

The Association, though, also realizes the significant moral and ethical implications that research on embryos may raise for both patients and physicians,<sup>123</sup> and asserts that physicians should not violate their own personal moral convictions.<sup>124</sup>

In the research context, physicians have a "greater responsibility to communicate fully with the patients who will participate in the research effort and the informed consent of those patients must meet the requirements of laws as well as the special level of professional responsibility dictated by ethical standards."<sup>125</sup> Additionally, the principles of the Declaration of Helsinki are applicable in the clinical research context.

The WMA also recommends that sex selection should not be done unless the intention is to avoid transmission of a sex-linked disease.<sup>126</sup> No other prohibitions or restrictions are specifically recommended by the Association. All activities, though, should be carried out "with appropriate respect for the health of... the embryo from the beginning of life."<sup>127</sup>

1. American College of Obstetricians and Gynecologists Committee on Ethics, "Ethical Issues in Human In Vitro Fertilization and Embryo Placement" ACOG Committee Opinion Number 47-July 1986. American College of Obstetricians and Gynecologists Committee on Ethics, "History, Scientific Background, and Ethical Considerations," Draft, 1993.
2. The Ethics Committee of the American Fertility Society, "Ethical Considerations of the New Reproductive Technologies" in 46(3) Fertility and Sterility, Supplement 1 1S-94S (1986).
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46. Id.
47. Id.
48. Id.
49. Id.
50. Id.
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52. Id.
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56. Id. at p. 9.
57. Id., at rec. 5.
58. Id., at rec. 1.
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# State Regulation of Embryo Research

by

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State legislative attention to research on the conceptus<sup>1</sup> is of a relatively recent vintage, dating back just twenty years. The event triggering the original legislative focus on such research was the U.S. Supreme Court decision, *Roe v. Wade*,<sup>2</sup> which recognized a woman's constitutional right to privacy to choose an abortion. It was presumed that this decision would lead to the increased availability of fetuses upon which to undertake research.<sup>3</sup> Some groups opposing abortion lobbied for restrictive state laws on fetal research in order that the social benefit available through research not be taken as a reason for supporting abortion.<sup>4</sup>

The influence of the availability of legal abortion on the regulation of fetal research is evident by the scope of the laws that were ultimately adopted. Twenty-five states have laws specifically aimed at the regulation of fetal research.<sup>5</sup> Twelve of these laws apply only to research with fetuses prior or subsequent to an elective abortion<sup>6</sup> and most of the statutes are either a part of or attached to abortion legislation.

The origins of the regulation in the abortion situation caused legislators to emphasize primarily research on later stage fetuses. The clear focus of the deliberations behind the existing legislation was research with abortuses which are not sufficiently well developed to live, but nonetheless temporarily exhibit some signs of life such as respiration. However, the language of some states' restrictions on research is sufficiently broad to cover the conceptus at a much earlier stage.

Now attention is once again being focused on research involving conceptuses—this time, not because of a legal development, but because of a series of scientific and medical developments. The roots of these developments were in the technique of *in vitro* fertilization, the *ex utero* fertilization of a woman's egg with a man's sperm in a petri dish.<sup>7</sup> *in vitro* fertilization itself was initially a research procedure and, although over the past 15 years it has become accepted as a standard medical practice, certain attempts to enhance the *in vitro* fertilization success rates are still considered to be research. These adjuncts to *in vitro* fertilization for infertile couples range from the relatively uncontroversial procedures of testing different media in which to fertilize the embryos to the more controversial techniques of embryo cryopreservation (freezing) for subsequent implantation<sup>8</sup> and embryo twinning (splitting the embryo).<sup>9</sup>

Beyond research focused on helping infertile couples conceive children, research has also been undertaken involving genetic screening of embryos.<sup>10</sup> These procedures provide couples with information on which to base decisions about whether or not to implant particular embryos.

The feasibility of genetic testing on embryos also leads to the theoretical possibility of undertaking gene therapy or other therapeutic measures to benefit either the embryo itself or the resulting child. Gene therapy on animal embryos has already been undertaken, but it has not yet been used on human embryos. There is increasing attention being paid to such a possibility within the scientific community, however.

Beyond procedures that might benefit the embryo or its progenitors, there are embryo research possibilities that would potentially benefit third parties. These include using the embryo as a source of cell lines or tissue.

There is also another category of embryo research. This is research that is not undertaken to benefit any particular individual, but to benefit society at large. Such research is basic scientific research, which might include the study of embryonic development or the study of the effect of particular interventions (such as exposure to certain drugs). The creation of embryos in petri dishes raises the possibility of using spare embryos for research purposes and the further possibility of creating embryos exclusively for research purposes.<sup>11</sup>

There is a wide range of opinions about the moral permissibility of various types of research on embryos. Yet embryo research, unlike fetal research, has not been the subject of extensive state legislative consideration. In part, this may have been due to the fact that fetal research was thought to entail mainly basic scientific research, while embryo research first came to the public's attention as part of a clinical procedure to aid infertile couples, a goal that many in society felt was laudable.<sup>12</sup>

Because embryo research *per se* has rarely been the subject of state legislative scrutiny, the analysis of whether a particular state restricts embryo research requires scrutiny of a wide range of state statutes which were adopted for other purposes, but contain language which is broad enough to regulate certain aspects of embryo research. These statutes include laws addressing fetal research, *in vitro* fertilization, tissue or organ transplantation, and payment for embryos. Not all the existing statutes, however, will necessarily survive constitutional scrutiny.<sup>13</sup> Some of the states' laws governing fetal research<sup>14</sup> and the disposition of fetal remains<sup>15</sup> have already been declared unconstitutional. In addition to the statutory precedents, criminal and tort law precedents in many states create an obligation on the part of scientists and clinicians to exercise due care when they undertake research or innovative therapy with respect to embryos and fetuses.<sup>16</sup>

## The Reach of the State Statutes

### State Fetal Research Statutes

In scientific terms, "embryo" and "fetus" are mutually exclusive categories; the term embryo refers to the conceptus prior to the end of eight weeks after fertilization and the term fetus refers to the conceptus after that point. However, state legislation does not pay attention to that distinction. Some state fetal research laws specifically define the term fetus or unborn child to include the embryo;<sup>17</sup> other state fetal research laws do not define the term fetus (and so arguably could apply to embryos). On the other hand, some states' laws specifically do not cover research on *ex utero* embryos. These include states with laws covering only research on *in utero* conceptuses or on conceptuses after they have developed certain vital signs,<sup>18</sup> or on conceptuses that have been the subject of an abortion.<sup>19</sup>

A close analysis of these laws indicates that only 10 of the 25 fetal research laws would apply to *ex utero* embryo research.<sup>20</sup> The laws of these states contain general prohibitions on embryo research (with enumerated exceptions in some of the states).<sup>21</sup>

The ten states that prohibit various forms of embryo research vary in their comprehensiveness and in the factors that are considered relevant in assessing whether a particular type of research is permissible. One seems to assume that embryo research is permissible. It provides, however, that no embryo that has been donated for research shall be transferred to a uterine cavity.<sup>22</sup> A few focus on the level of risk to the embryo—for example, by allowing harmless research<sup>23</sup> or forbidding only research that will substantially jeopardize the health or life of the fetus.<sup>24</sup> Some of the statutes consider the purpose of the research—for example, by prohibiting nontherapeutic research<sup>25</sup> or by permitting *in vitro* fertilization<sup>26</sup> or by allowing procedures to diagnose or remedy a problem in the embryo.<sup>27</sup> (See Appendix A for a state-by-state description of the laws on embryo research. See Table I for a state-by-state chart on embryo research and commercialization.)

### In Vitro Fertilization (IVF) Laws

There are far fewer state laws specifically addressing the conduct of *in vitro* fertilization than addressing the conduct of fetal research. Although the impetus behind the laws was, for the most part, the regulation of the clinical practice of *in vitro* fertilization, the provisions are broad enough to regulate researchers who work with embryos created *in vitro*. Thus, certain laws governing reporting, the qualifications of personnel, and so forth, will be applicable to researchers as well as clinicians. A New Hampshire law requires counseling in advance of *in vitro* fertilization and limits the procedure to women over age 21.<sup>28</sup> Pennsylvania has a reporting requirement which mandates that anyone performing *in vitro* fertilization file quarterly reports with the Department of Health describing such facts as the number of embryos destroyed and discarded and the number of women in whom embryos are implanted.<sup>29</sup> Louisiana has a law requiring that IVF shall only be undertaken by practitioners and facilities meeting the standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS).<sup>30</sup> Some states have statutes dealing with insurance reimbursement of *in vitro* fertilization for infertility. A few of those states mandate that, to be reimbursed, the *in vitro* fertilization procedure must be performed in facilities that meet the ACOG and AFS standards.<sup>31</sup> Such provisions would be relevant to IVF clinicians who are also undertaking research (for example, by undertaking embryo cryopreservation in conjunction with *in vitro* fertilization) and researchers working with excess embryos.

The *in vitro* fertilization law of most relevance to issues of embryo research is a Louisiana statute. The statute comprehensively regulates the experimental use of *in vitro* fertilized ova and embryos produced by *in vitro* fertilization.<sup>32</sup> The Louisiana statute defines a “human embryo” as “an *in vitro* fertilized human ovum ... composed of one or more living human cells and human genetic material so unified and organized that it will develop *in utero* into an unborn child.”<sup>33</sup> Before implantation, an *in vitro* fertilized ovum is a juridical person<sup>34</sup> with rights to sue or be sued,<sup>35</sup> and to confidentiality.<sup>36</sup>

Such embryos are to be used “solely for the support and contribution of the complete development of human *in utero* implantation.”<sup>37</sup> The statute forbids selling *in vitro* embryos and culturing or farming them solely for research or any other purpose.<sup>38</sup> The statute also forbids any person to destroy a viable embryo.<sup>39</sup>

In addition to restricting experimental use of an *in vitro* embryo, the Louisiana statute specifies its relation to other persons and the duties owed by others to it. An *in vitro* embryo is not property.<sup>40</sup> If *in vitro* patients reveal their identities, their rights as parents of the fertilized ovum are preserved; otherwise, the physician or a court-appointed curator is its guardian.<sup>41</sup> The gamete donors owe the *in vitro* embryo a "high duty of care and prudent administration."<sup>42</sup> They may renounce their rights generally, in which case the embryo is placed for "adoptive implantation," or in favor of a couple willing and able to accept it.<sup>43</sup> Neither couple may pay or receive compensation to renounce parental rights.<sup>44</sup> Disputes involving the embryo are to be determined by its best interests.<sup>45</sup>

The physician who caused the *in vitro* fertilization is directly responsible for the embryo's safekeeping *in vitro*.<sup>46</sup> The physician, hospital, and clinic are not strictly liable for any screening, collection, conservation, preparation, transfer, or cryopreservation procedure undertaken in good faith. This immunity, however, appears only to actions brought on behalf of *in vitro* embryo as juridical persons.<sup>47</sup>

### **Payment for Embryos**

There is considerable state legislation affecting whether embryos may be sold for research purposes or other purposes.<sup>48</sup> Twelve states explicitly or implicitly ban payment for embryos for any purpose.<sup>49</sup> Four ban payment for embryos for research purposes.<sup>50</sup> Five ban payment for body parts for transplantation in language broad enough to apply to embryos,<sup>51</sup> while three others ban payment for an enumerated list of body parts that does not include embryos or embryonic tissue but can be amended to include it by agency decision.<sup>52</sup>

## **Effects of State Laws on Particular Types of Research**

### **Embryo Cryopreservation or Donation**

Health care providers performing embryo cryopreservation<sup>53</sup> on embryo donation<sup>54</sup> as part of *in vitro* fertilization will, in Pennsylvania,<sup>55</sup> have to comply with the statutes on reporting. In Louisiana they will have to comply with the law regarding the personnel qualifications and in certain other states, they will have to comply with insurance laws specifying the qualifications of reimbursable IVF providers.<sup>56</sup>

Because both procedures still are arguably experimental, there is also a concern that they will run afoul of the embryo research or IVF laws in certain states. Five states have laws which could be used to prohibit embryo cryopreservation<sup>57</sup> and five states have laws which could be interpreted to prohibit embryo donation.<sup>58</sup>

Embryo twinning is even more experimental. Embryos can be divided in half before implantation in order to enhance the probability of at least one live birth. The procedure is risky for the embryo, however, and could violate the bans on embryo research in eight states.<sup>59</sup>

## Preimplantation Genetic Screening

Various prenatal diagnostic techniques have been developed to help the couple<sup>60</sup> decide whether or not to continue a particular pregnancy. Research on genetic testing of *ex utero* embryos is currently underway.<sup>61</sup>

Six states specifically allow genetic screening, exempting the procedure from their bans on embryo research.<sup>62</sup> In four other states, preimplantation genetic screening would be prohibited unless it could be shown to be beneficial or riskless to the embryo.<sup>63</sup>

In addition to the general embryo research bans that extend to preimplantation screening, the laws of at least two other states could conceivably affect this procedure. These laws do not apply to other types of embryo research, but may, through a quirk in their language, apply to preimplantation screening. They are statutes that prohibit research *prior to* an abortion or on a conceptus intended to be aborted.<sup>64</sup>

## Gene Therapy and Other Treatment for Embryos

The prospect of adding genetic material to an embryo *in vitro* has been suggested as a way to correct genetic defects. Because the goal of the procedure is to provide a health benefit to the embryo or the resulting child, it is likely to be permissible even in states with extremely restrictive general bans on embryo research. Eight of the state laws governing embryo research would seem to allow gene therapy on embryos.<sup>65</sup> Two others appear to prohibit it.<sup>66</sup>

## Cell Line Development

All of the ten states that have laws banning embryo research<sup>67</sup> would appear to prohibit the development of cell lines out of embryos, if the procedure is considered a research procedure, since it would not be seen as therapeutic or beneficial to the embryo. In addition, payment for the cell lines might violate the laws in states banning payment for embryos for research uses or for any uses.

An argument might be made that certain types of cell line development should not be considered to be research, but rather an accepted practice (taking them out of the reach of the research bans).<sup>68</sup> At that point, the question of whether companies could commercialize the cell lines would depend on whether there is a state law banning payment for cell lines or for fetal parts for any uses (not just research uses).

While some state laws might prevent payment for embryonic cell lines, it is possible that because a cell line is new tissue produced from the genetic material of, but not originally a part of, the embryo, laws proscribing the sale of embryonic tissue may not apply. In fact, a Minnesota law prohibits the sale of living conceptuses or nonrenewable organs but does allow "the buying and selling of a cell culture line or lines taken from a non-living human conceptus...."<sup>69</sup> In contrast, Nevada's broadly worded statute making it a crime for anyone to use or "make available ... the remains of an aborted embryo or fetus for any commercial purpose" could conceivably outlaw the production of cell lines from fetal tissue.<sup>70</sup>



## Basic Scientific Research

The statutes which totally prohibit nontherapeutic research on embryos could seriously impede development of diagnostic and treatment technologies that would ultimately benefit other embryos. Some use broad enough language that they could be interpreted to ban research even if there is no risk to the embryo—for example, observational studies of embryonic development. Yet an understanding of the normal situation and the range of variation must precede the definition of the abnormal. For example, the development of the tests to be used in conjunction with amniocentesis were made possible by undertaking research that was nonbeneficial to the researched-upon fetus (such as the assessment of the level of certain enzymes in its amniotic fluid), but which was able to provide a typology for normal and abnormal values.

It would be a mistake to assume that nontherapeutic research is invariably more risky than potentially therapeutic research. For example, there will be more risk involved in gene therapy (which is intended to be therapeutic) than in studies which involve only observations and the collection of data on embryonic development. The ethical evaluation of research on embryos should involve a consideration both of the purposes of the activities and the risk involved as an effect of these activities; and these two factors, the purpose and the effect, should be kept conceptually distinct. The extent and magnitude of risk to a research subject is not correlated to the purpose of the activity or in some way determined by whether or not the activity is intended to provide a health benefit.

The study of conceptuses has potential relevance in many areas of medicine, including cancer research (because cell division of conceptuses resembles cell division in cancer tumors) and contraceptive research (because understanding the mechanism of embryo development and implantation can lead to the development of ways to inhibit them). The creation of embryos in petri dishes occasioned by the development of *in vitro* fertilization raises the possibility of using spare embryos for research purposes and the further possibility of creating embryos exclusively for research purposes.<sup>71</sup>

Research on the conceptus without an identifiable intended beneficiary seems to offer a more remote benefit than does research to benefit the conceptus, or the gamete providers. Nevertheless, medical knowledge has been gained through general research on conceptuses. Much information can be obtained through research on animals, but human research is ultimately necessary because of the unique functioning of humans. Rubella vaccination research in monkeys demonstrated that the vaccination did not cross the placenta, yet subsequent human research revealed that it did and thus was unsafe for use in pregnant women.<sup>72</sup>

Nine states forbid general scientific research on embryos.<sup>73</sup> Certain state laws would also forbid payment to women in exchange for donating their conceptuses for general scientific research. Ironically, although the benefits may be seen as more remote with pure scientific research than with tissue transplantation to an identifiable recipient, there are fewer laws that would prohibit payment in conjunction with pure research. Fifteen states ban payment for embryos used in scientific research,<sup>74</sup> while between 16 and 19 states ban payment in connection with donation of tissue or organs for transplantation.<sup>75</sup>

## Constitutionality of Statutes Restricting Embryo Research

Not all regulations on research are constitutional. Laws restricting research may be struck down as too vague or as violating the equal protection clause. Those affecting couples' reproductive choices may violate the right to privacy. In addition, some legal commentators posit that there is a constitutional right to undertake or participate in research. Even if undertaking and participating in research were constitutionally protected, however, certain restrictions on research to further health and safety would be constitutionally permissible.

### The Reach of the Couple's Right to Privacy

Statutes that do not allow the use of experimental genetic and reproductive technologies would be open to constitutional challenge. Such a challenge was successful in a federal district court case, *Lifchez v. Hartigan*,<sup>76</sup> which held that a ban on research on conceptuses was unconstitutional because it impermissibly infringed upon a woman's fundamental right to privacy. Although the Illinois statute banning embryo and fetal research permitted *in vitro* fertilization, it did not allow embryo donation, embryo freezing, or experimental prenatal diagnostic procedures. The court stated:

It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy. Chorionic villi sampling is similarly protected. The cluster of constitutional choices that includes the right to abort a fetus within the first trimester must also include the right to submit to a procedure designed to give information about that fetus which can then lead to a decision to abort.<sup>77</sup>

The *Lifchez* case also held that the ban on experimentation on embryos was unconstitutionally vague because it failed to define the terms "experimentation" and "therapeutic."<sup>78</sup> The court pointed out that there are multiple meanings of the term "experimentation."<sup>79</sup> It could mean pure research, with no direct benefit to the subject. It could mean a procedure that is not sufficiently tested so that the outcome is predictable, or that departs from present-day practice. It could mean a procedure performed by a practitioner or clinic for the first time. Or it could mean routine treatment on a new patient. Since the statute did not define the term, it violated researchers' and clinicians' due process rights under the fifth amendment since it forced them to guess whether their conduct was unlawful.<sup>80</sup>

A similar result was reached by a federal appellate court assessing the constitutionality of a Louisiana law prohibiting nontherapeutic experimentation on fetuses in *Margaret S. v. Edwards*. The appeals court declared the law unconstitutional because the term "experimentation" was so vague it did not give researchers adequate notice about what type of conduct was banned.<sup>81</sup> The court said that the term "experimentation" was impermissibly vague<sup>82</sup> since physicians do not and cannot distinguish clearly between medical experimentation and medical tests.<sup>83</sup> The court noted that "even medical treatment can be reasonably described as both a test and an experiment."<sup>84</sup> This is the case, for example, "whenever the results of the treatment are observed, recorded, and introduced into the data base that one or more physicians use in seeking better therapeutic methods."<sup>85</sup>

A contrary result was reached by a federal district court in Utah which considered the constitutionality of Utah law banning embryo and fetal experimentation in *Jane L. v. Bangerter*.<sup>86</sup> The law, which provided that "unborn children may not be used for experimentation," was challenged

as violating the right to privacy by proscribing experimental therapies intended to benefit a woman or her unborn child. In a bit of linguistic gymnastics, the court read into the law an exception for techniques to benefit the woman or the child (which presumably would cover techniques such as cryopreservation, twinning, and embryo donation, which are intended to benefit a woman by enhancing her opportunities for pregnancy, and gene therapy, which is intended to benefit the child). According to the court,

The plain meaning of the statutory prohibition, as denoted by the phrase “used for experimentation,” is to protect unborn children from tests or medical techniques which are designed solely to increase a researcher’s knowledge and are not intended to provide any therapeutic benefit to the mother or child.<sup>87</sup>

The court also used its interpretation of the statute to uphold the law against a challenge that it was impermissibly vague. It held that the problems of defining “experimentation,” inherent in the statutes at issue in *Margaret S.* and *Lifchez* were not present in the Utah law. By interpreting the term “used for experimentation” to mean used *solely* for experimentation, the court held that,

[A] physician is not required to determine whether or not a particular medical procedure is experimental. The statute, by its plain terms, requires only that a physician determine whether a procedure is performed merely to increase general knowledge, or performed to benefit the pregnant woman or the unborn child. As long as there is intent to benefit the fetus or the mother, the fetus is not being “used for experimentation.”<sup>88</sup>

## Potential Right to Undertake Research

The cases thus far indicate that the existing embryo research statutes might be vulnerable to attack on the grounds that they violate the right to privacy or are unconstitutionally vague. If a state were to adopt a more precisely-tailored law that did not implicate reproductive decisions (such as a law banning certain specific types of general scientific research), it would likely be upheld as constitutional. However, at least some commentators would argue that the U. S. Constitution precludes eliminating certain lines of research altogether.

Although there is no specifically enumerated right to research in the U.S. Constitution, commentators such as John Robertson argue that support for such a right could be derived from the fourteenth amendment right to personal liberty<sup>89</sup> and the first amendment right to free speech.<sup>90</sup> This right to research consists of the freedom to pursue knowledge and the freedom to choose the means to achieve that knowledge.<sup>91</sup> The Supreme Court stated in *Meyer v. Nebraska*<sup>92</sup> that the right to liberty guaranteed by the fourteenth amendment encompassed freedom to “acquire useful knowledge ... and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.”<sup>93</sup> This language arguably applies not only to the researcher’s right to scientific inquiry, but also to an individual’s right to participate as a research subject.<sup>94</sup>

Robertson hinges most of his argument on the first amendment’s protection of free speech which he believes includes a right to learn new information. However, Robertson distinguishes the freedom to pursue knowledge from the right to choose the method for achieving that knowledge, since the method itself may permissibly be regulated.<sup>95</sup> Although Robertson argues that the government may not prohibit research in an attempt to prevent the development of new knowledge, he recognizes

that it may restrict or prohibit the means used by researchers which intrude on interests in which the state has a legitimate concern.<sup>96</sup> Therefore, both the federal government and the state may regulate the researcher's methods in order to protect the rights of research subjects and community safety.<sup>97</sup> Research may be restricted, for example, to protect the subject's right to autonomy and welfare by requiring informed, free and competent consent.<sup>98</sup> However, argues Robertson, the state cannot arbitrarily regulate research solely because it deems the knowledge sought to be obtained distasteful or subject to harmful use.<sup>99</sup>

## **Developing Policies for Embryo Research**

Policies which embody an evaluation of the risks and benefits of various types of embryo research are difficult to develop in part because there is widespread and deep disagreement concerning the moral significance of embryos and the morally legitimate reasons for placing them at risk.

The previous sections have described the range of laws which affect embryo research, the application of the laws to specific technologies, and the constitutional challenges that might be waged against the statutes. As attempts are made to develop new policies to cover research on embryos, though, a number of characteristics of the research, the embryo, and the intended beneficiaries of the research may be useful to consider in assessing what provisions are appropriate for the policies.

Considering factors that have been deemed relevant under one or more of the existing state laws is a way to begin the task of recommending new policies. These factors include:

- Appropriate previous animal research
- Advance review
- Consent to research
- Purpose of the research
- Stage of development of the embryo
- Whether it is intended that the embryo go to term
- Level of risk to the embryo or resulting child

It is also important to consider implementational aspects, such as how "embryo" and "research" will be defined, what the penalties should be for violation of the policy, and what enforcement mechanisms will be necessary.

### **Appropriate Previous Animal Work**

Various ethical<sup>100</sup> and legal<sup>101</sup> guidelines regarding human research emphasize the importance of previous research on animals. Although no state law specifically requires previous animal research before *embryo* research is undertaken, such an approach would seem to be appropriate. Under a New

Mexico law, there must have been appropriate studies on animals before research is undertaken on later-stage fetuses.<sup>102</sup>

## Advance Review

Concern for the rights of human subjects who participate in medical research spurred the development of Institutional Review Boards.<sup>103</sup> The idea of requiring review and approval of a research project by an independent body before it was initiated grew out of a concern that relying on the investigator's sense of professional responsibility was an insufficient safeguard of the human subject's rights.<sup>104</sup> If research on embryos is federally funded, advance review by an Institutional Review Board would be required.<sup>105</sup> No matter what the source of funding, the Massachusetts law governing embryo research implies that there must be an assessment by an Institutional Review Board.<sup>106</sup>

## Consent to Research

A cornerstone of research on human subjects is that consent is necessary before research may be undertaken. With respect to embryo research, the researched-upon subject is not capable of giving consent, so a policy decision must be made about who should be asked for permission to undertake research on the embryo.

There is a consensus that at least the woman who provided the egg for fertilization should be asked for permission before research is undertaken involving her embryo. There is some evidence that, in earlier studies, the woman's consent was not always sought. Embryos removed during the course of medical procedures, such as hysterectomies, have apparently been used without the knowledge or consent of the women undergoing the procedures.<sup>107</sup> Experimentation on a woman's embryo without her consent can create psychological harm to women.<sup>108</sup> It can also pose potential physical harm to particular women since, if they do not realize research is intended for the fetus, they may not question potentially risky medical procedures undertaken on them to facilitate the research.<sup>109</sup>

In the context of fetal research, it was originally argued that the woman who has decided to abort the fetus is not an appropriate person to give a proxy consent for research on it.<sup>110</sup> Her decision to abort was taken as a sign of abandonment or inability to act in the fetus' best interest. However, since women have a constitutional right to abort, taking away her right to consent to or refuse research because she exercised that right may be an unconstitutional penalty.<sup>111</sup> Similarly, the fact that a couple does not wish to create a pregnancy with an excess embryo should not be taken to signify that they have somehow "abandoned" the embryo and waived all decisionmaking rights.<sup>112</sup>

In most infertility clinics, the consent form for *in vitro* fertilization discloses when a particular technique is experimental and asks for the progenitors' consent to do the procedure. Even with respect to excess embryos that the couple do not plan to use to create children, embryo research is not undertaken without the couple's explicit consent.<sup>113</sup>

None of the state statutes affecting embryo research address the type of information that must be provided to the progenitors before they are asked for consent. In contrast, other guidelines for human research emphasize providing information about the nature of the research, its purpose, and the effect on the subject. Of the state statutes governing *fetal* research, only New Mexico's statute

describes the information that must be given before consent to research involving a fetus is valid. Under the New Mexico law, a woman who is asked to participate in research must be “fully informed regarding possible impact on the fetus.”<sup>114</sup> While the New Mexico law does not cover research on embryos, it does provide guidance for what type of information might be necessary in soliciting an informed consent.

## **The Purpose of the Research**

Some state statutes take into consideration the purpose of the research. For example, under eight of the ten embryo statutes, research which is therapeutic to the embryo is permissible.<sup>115</sup>

Certain state laws also appear to recognize the special nature of research to meet the reproductive needs of potential parents. The Pennsylvania law banning experimentation on unborn children, for example, has an exception for *in vitro* fertilization.<sup>116</sup> Five of the nine states banning embryo research have exceptions allowing experimental genetic diagnostic techniques. The Utah statute states that “[l]ive unborn children may not be used for experimentation, but when advisable, in the best medical judgment of the physician, may be tested for genetic defects.”<sup>117</sup> The laws of four states, Massachusetts, Michigan, North Dakota, and Rhode Island, explicitly do not apply to diagnostic procedures aimed at determining the health of a fetus.<sup>118</sup>

## **Stage of Development of the Embryo**

There is a growing consensus around the world that embryo research is permissible in the earliest stages after fertilization. Governmentally appointed commissions in Great Britain (the Warnock Committee),<sup>119</sup> in Victoria, Australia (the Waller Committee),<sup>120</sup> and in Ontario, Canada (the Ontario Law Reform Commission),<sup>121</sup> for example, have found embryo research to be ethically acceptable during the first 14 days of life.

The first 14 days of development are thought to be biologically distinct from later stages of development and that biological distinction is thought by some to justify less restrictive regulations for research in the two weeks following fertilization. During that time, the embryo’s cells relate primarily to physiological interaction with the mother, rather than the development of the embryo itself. After this point, the cells relate to the embryo and the cells are committed to forming a single individual (rather than, for example, twins).<sup>122</sup>

The recommendation that research be allowed in the first 14 days after fertilization raises the possibility that future state policies will regulate more finely by developing different standards for different stages of development of the conceptus. The two week period after fertilization, for instance, may be considered to be unique for purposes of regulation. In addition, the stage of development at which the conceptus begins to feel pain<sup>123</sup> might also provide a point at which research responsibilities change.

One example of a continuum of standards for research on *ex utero* embryos and fetuses depending on their stage of development is suggested by John Wilson.<sup>124</sup> He suggests that nontherapeutic research for minimally justifiable reasons be permitted until the point brain wave activity can be measured (6 to 8 weeks). From then until about 18 weeks he would allow

nontherapeutic research with a greater justification (such as the development of important vaccines). After 18 weeks, he would permit only therapeutic research.

Currently, however, state laws affecting embryos do not focus on the first 14 days of development. However, some laws governing research of fetuses do turn on developmental stages late in pregnancy. Thus, a number of laws regulate only research on fetuses that exhibit some vital signs that make it seem similar to a live born infant.<sup>125</sup>

### **Whether or Not the Embryo Will Go to Term**

Questions arise regarding whether more types of research and/or procedures of a greater risk should be used on embryos which are not intended to go to term.<sup>126</sup> A parallel, although not entirely analogous debate, arose in the context of fetal research, raising questions about whether more risky research was permissible on an *in utero* fetus that a pregnant woman intended to abort than on one that would be brought to term.

In the mid-1970's, the National Commission for the Protection of Human Subjects came to the consensus that fetuses to be aborted and fetuses to be carried to term have equal rights to respect, and that therefore they are deserving of equal treatment or of an equal standard of protection.<sup>127</sup> A federal statute specifically provides that, in federally funded research, the same risk standard be used for fetuses which will be aborted and fetuses which will go to term.<sup>128</sup> However, there is disagreement about what it means to treat these two classes of fetuses equally or according to the same standard.<sup>129</sup> According to some, the equality principle when applied to these two classes means allowing the same range of procedures with respect to both classes of fetuses. No procedure should be undertaken upon fetuses to be aborted which cannot legitimately be undertaken with fetuses going to term.

According to an alternative understanding of the equality principle as it applies to fetal research, "equal treatment" refers not to the spectrum of procedures but to the level of risk imposed. According to those who make this argument, though the two classes of fetuses do have the same moral status and are therefore deserving of the same level of respect, some procedures may be undertaken with fetuses to be aborted that may not be undertaken with fetuses going to term provided that there is no more risk imposed on the one class than on the other. An example noted by the National Commission is research which seeks to determine whether or not a drug crosses the placenta. Consider the case where a drug administered to a pregnant women does not affect fetal tissue for several weeks. If the fetus is aborted before it can be affected, this research poses no risk of harm; the ability to be harmed has already ceased before the specific harmful effects of this drug would occur. However, where the fetus is to be born, such an experiment could potentially cause damage. Various members of the Commission argued that in research such as this, the fetuses to be aborted could be subject to procedures which would be wrong to undertake upon fetuses going to term.<sup>130</sup> Their reasoning is based on the notion that equal protection does not mean that the range of appropriate procedures is identical for both classes of fetuses but instead that the risk of harm should be no greater to one group than to the other and that in certain cases this might justify a different range of acceptable procedures for the two groups.

Persons who hold this view attempt to clearly distinguish it from the notion that harm to the fetus is relative to its prospects for survival. As Karen Lebacqz points out, "one must not mistake this (the argument that equal protection means equal risk) as an argument that 'since the fetus is going

to die anyway, it doesn't matter what is done to it.'"<sup>131</sup> Her point is that the fact that a fetus will soon die does not alter its value while it is still alive.

When research is being undertaken on a fetus *in utero*, a potential danger in allowing a different type of research on a fetus that is scheduled to be aborted is that a woman may change her mind about the abortion, potentially bringing to term a fetus that has been damaged by the research intervention. With respect to the embryo *ex utero*, there may be less of a chance that the woman will change her mind and actually ask that the experimented-upon embryo be implanted if she initially donated the embryo to a research protocol that did not involve implantation. And, unlike in the case of an *in utero* fetus, research on an *ex utero* embryo could be undertaken in a manner that did not allow the possibility of women later reclaiming their embryos for implantation. If the woman specifically gave consent for research to be undertaken on her embryo in a manner in which her embryo was not identified and would not be brought to term, such as in a protocol in which embryos from a number of other women were also used and not linked in an identifiable way to the progenitors, there would be little chance the woman would be able to convince a judge to give her researched-upon embryo back to her for implantation.

## The Level of Risk

The level of risk of the research to the fetus, while pivotal in the federal regulations, is of importance under only a few states' statutes. Under four states' embryo research statutes, nontherapeutic research is allowed on embryos that are not the subject of a planned abortion so long as the research does not substantially jeopardize the life or health of the fetus<sup>132</sup> and, in another state, nontherapeutic research on embryos is allowable if it is harmless.<sup>133</sup>

The difficulty with having the permissibility of fetal research hinge on the level of harm involved is that it is hard to predict harm without some research in the first place. And, in fact, beneficial information has come from research designed to assess risk, such as one project which administered rubella vaccines to pregnant women who were going to abort and then assessed whether the vaccine crossed the placental barrier.<sup>134</sup> Yet research undertaken with the goal of assessing the risk of harm entailed by a certain drug or procedure is often viewed as inappropriate. A 1972 report of a governmentally appointed commission in Great Britain, for example, stated that "[i]t is unethical to administer drugs or carry out any procedures during pregnancy with the deliberate intent of ascertaining the harm they might do to the fetus."<sup>135</sup>

## Procedural Aspects

The initial policy question in this area will be definitional—that is, the determination of which conceptuses the policy will cover. There are three alternatives to take with respect to such a classification. One would be to have the policy track the scientific distinction and cover all embryos through the eighth week after fertilization, whether they were *in utero* or *ex utero* and whether they were created through *in vivo* fertilization or *in vitro* fertilization. A second approach would be to cover embryos only until the point of implantation, whether they were *in utero* or *ex utero* and whether they were created through *in vivo* fertilization or *in vitro* fertilization. This approach has some appeal since it would complement the existing federal regulations which define a fetus as starting with implantation and regulate research after that point.<sup>136</sup> A third, and probably preferable



approach, would be to target only *ex utero* embryos, since they raise particular concerns and are potentially subject to a wide array of research interventions.

Beyond defining embryo for purposes of the proposed policy, it is necessary to have a definition of research. One of the greatest constitutional vulnerabilities of the current statutes is that they do not adequately define research or experimentation and thus give inadequate notice of the types of behaviors that are prohibited under the law. Already, two federal courts have declared fetal research statutes unconstitutional on those grounds.<sup>137</sup>

## **Penalties and Enforcement Mechanisms**

A determination should also be made about penalties and enforcement mechanisms of any embryo research policies that are created. The states vary in the type of penalties they impose for violation of the fetal research laws. In some states, violation of the fetal research law is considered to be unprofessional conduct,<sup>138</sup> creating the potential for a physician/researcher who violates the law to lose his or her license to practice medicine. In other jurisdictions, the violation of the laws can subject the researcher to a fine and imprisonment.<sup>139</sup>

The Massachusetts statute creates an elaborate regulatory mechanism providing for public and private actions to enforce the law. When a proposal for research on embryos or fetuses is approved, the written approval by the Institutional Review Board must be filed with the local District Attorney.<sup>140</sup> The approval is open for public inspection. If the District Attorney believes that the proposed procedure is prohibited, he or she shall file a complaint, giving notice to the Commissioner of Public Health, who in turn gives notice to all licensed medical schools and other institutions in the state who may be affected by a judgment in the case.<sup>141</sup> The statute authorizes a broad class of people or institutions potentially affected by the judgment to intervene in the case.<sup>142</sup> The trial on the merits must be without a jury,<sup>143</sup> and any judgment must be published in newspapers and sent to licensed hospitals and medical schools.<sup>144</sup> There is also a procedure for researchers to bring a declaratory judgment action to determine whether a proposed procedure violates the provisions of the statute.<sup>145</sup>

## **Conclusion**

The state laws covering embryo research provide some guidance for federal policies in the area. However, none of the existing laws are sufficiently comprehensive or supportable to serve as a complete model for future policy-making efforts in this area.

## **Notes**

1. I use the term "conceptus" to refer to the product of human conception from fertilization until birth. Much confusion has been generated by the terms used to describe the conceptus in the various stages of development. In scientific terms, a fertilized egg passes through the stages of being a zygote, morula and blastocyst and then, from about the end of the second week of development until the end of the 8th week, it is an embryo. For the rest of the pregnancy, it is a fetus. The legal writings have not been so precise, however. In legal contexts, the term "embryo" has been used to refer to the conceptus from fertilization until the end of the 8th

week and the term fetus has been used to refer to the conceptus in all stages of development. The conceptus thus encompasses both the embryo and the fetus.

2. Commentators have generally viewed the decision in *Roe v. Wade*, 410 U.S. 111 (1973), as playing a determinative role in the history of the fetal research controversy. See, e.g., Note, "Fetal Experimentation: Moral, Legal, and Medical Implications," 26 *Stan. L. Rev.* 1191, 1191 n.2 (1974) (hereinafter "Fetal Experimentation"); Note, "Fetal Research: A View from Right to Life to Wrongful Birth," 52 *Chi.-Kent L. Rev.* 133 (1975) (hereinafter "Fetal Research"); Comment, "The Future of Fetal Research in California: A Proposal for Change," 15 *San Diego L. Rev.* 859, 863-864 (1978); and Baron, "Legislative Regulation of Fetal Experimentation: On Negotiating Compromise in Situations of Ethical Pluralism" in A. Milunsky and G. J. Annas, eds., *Genetics and the Law III* 431, 432 (1985). Robert Levine has argued that the *Roe* decision did not alter the possibilities for research by creating a surplus of research subjects as is often thought but did have a decisive effect by facilitating certain categories of research. However, he also points out that a liberal abortion law may hamper research since it encourages earlier abortions and thus may lessen the number of fetuses at an appropriate stage of development. Levine, "The Impact on Fetal Research of the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research," 22 *Vill. L. Rev.* 367, 370 (1976-77).
3. Whether or not the decision increased the *number* of fetuses available for research, it is certainly the case that the decision meant that more fetuses are aborted in medical facilities of the sort where research is conducted.
4. For a discussion of the history of the state fetal research laws, see Nathan, "Fetal Research; An Investigator's View," 22 *Vill L. Rev.* 384, 386 (1976-77).
5. Ariz. Rev. Stat. Ann. §36-2302, -2303 (1986); Ark. Stat. Ann. §20-17-801, -802 (1991); Cal. Health & Safety Code §25956, 25957 (West 1984); Fla. Stat. Ann. §390.001(6), (7) (West 1986); Ind. Code Ann. §35-1-58.5-6 (West 1986); Ky. Rev. Stat. §436.026 (1985); La. Rev. Stat. Ann. §9:121 et seq. (1991); Me. Rev. Stat. Ann. tit. 22, §1593 (1992); Mass. Ann. Laws ch. 112, §12J (Law. Co-op. 1991); Mich. Comp. Laws Ann. §§333.2685, -2692 (West 1992); Minn. Stat. Ann. §145.421 to -.422 (West 1989); Mo. Ann. Stat. §188.037 (Vernon 1983); Mont. Code Ann. §50-20-108(3) (1991); Neb. Rev. Stat. §§28-342 to -346 (1989); N.H. Rev. Stat. Ann. sec 168-b:15 (Cum. Supp. 1993); N.M. Stat. Ann. §24-9A-1 et seq. (1991); N.D. Cent. Code §14-02.02-01, -02 (1991); Ohio Rev. Code Ann. §2919.14 (Baldwin 1992); Okla. Stat. Ann. tit. 63, §1-735 (West 1987); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws §11-54-1 (Supp. 1993); S.D. Codified Laws Ann. §34-23A-17 (1986); Tenn. Code Ann. §39-15-208 (1991); Utah Code Ann. §§76-7-310 (1990); and Wyo. Stat. §35-6-115 (1988).
6. Ariz. Rev. Stat. Ann. §36-2302(A) (1986) (subsequent); Ark. Stat. Ann. §20-17-802 (1991) (subsequent); Cal. Health & Safety Code §25956(a) (West 1984) (subsequent); Fla. Stat. Ann. §390.001(6) (West 1986) (prior or subsequent); Ind. Code Ann. §35-1-58.5-6 (West 1986) (subsequent); Ky. Rev. Stat. §436.026 (1985) (subsequent); Mo. Ann. Stat. §188.037 (Vernon 1983) (prior or subsequent); Neb. Rev. Stat. §28-346 (1989) (subsequent); Ohio Rev. Code Ann. §2919.14(A) (Baldwin 1992) (subsequent); Okla. Stat. Ann. tit. 63, §1-735(A) (West 1987) (prior or subsequent); Tenn. Code Ann. §39-15-208 (1982) (subsequent); Wyo. Stat. Ann. §35-6-115 (1988) (subsequent).

7. This technique first resulted in a live birth in 1978. See R. G. Edwards, P. C. Steptoe, and J. M. Purdy, "Establishing Full-Term Human Pregnancies using Cleaving Embryos Grown *In Vitro*," 87 *British Journal of Obstetrics and Gynecology* 737 (1980).
8. See, e.g., Gerald H. Zeilmaker *et al.*, "Two Pregnancies Following Transfer of Intact Frozen-Thawed Embryos," 42 *Fertility and Sterility* 293 (1984).
9. This procedure is done to enhance the chances of pregnancy.
10. See, e.g., J. Simpson and S. Carson, "Editorial: Preimplantation Genetic Diagnosis," 327 *New Eng. J. Med.* 951 (1992).
11. See, e.g., C. Grobstein, *From Chance to Purpose: An Appraisal of External Human Fertilization* 1 (1981).
12. See the accompanying international paper, which describes the widespread international acceptance of *in vitro* fertilization for infertility.
13. For a discussion of the constitutionality of laws, see text at notes 76 to 99, *infra*.
14. *Lifchez v Hartigan*, 735 F. Supp. 1361 (N.D. Ill.), *aff'd* 914 F. 2d 260 (7th Cir. 1990), *cert. denied sub nom.*, *Scholberg v. Lifchez*, 498 U.S. 1069 (1991); *Margaret S. v. Edwards*, 794 F. 2d 994 (5th Cir. 1986); *But see Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah).
15. *Margaret S. v. Edwards*, 794 F. 2d 994 (5th Cir. 1986).
16. For a discussion of these precedents, see Lori B. Andrews, "The Legal Status of the Embryo," 32 *Loy. L. Rev.* 357 (1986).
17. Under Kentucky law, for example, a fetus is a human being from fertilization until birth. Ky. Rev. Stat. §311.720(5) (1985). Similarly, Missouri law defines an "unborn child" as "the offspring of human beings from the moment of conception until birth at every stage of its biological development including the human conceptus, zygote, morula, blastocyst, embryo, and fetus." Mo. Ann. Stat. §188.015(6) (Vernon Supp. 1993).
18. For example, the Arkansas fetal research law prohibits nontherapeutic research on an aborted fetus born alive (Ark. Stat. Ann. §20-17-802(b)(1) (1991)), but allows it on an aborted fetus born dead if the mother consents (§20-17-802(b)(2)). The Arkansas statute defines a "dead fetus" as "a product of human conception exclusive of its placenta or connective tissue, which has suffered death prior to its complete expulsion or extraction from the mother as established by the fact that, after the expulsion or extraction the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles." *Id.*, §20-17-801(b)(2). Thus it appears that *ex utero* fetuses in the earlier developmental stages are permissible subjects for research so long as the mother consents. Similarly, in California, nontherapeutic research on aborted fetuses is permissible if the fetus is "lifeless," which is defined to mean that the fetus has no discernible heartbeat. Cal. Health & Safety Code §25956(a) (West 1984). In addition, the New Mexico restriction on research only applies if the fetus exhibits either heartbeat, spontaneous respiratory activity,

spontaneous movement of voluntary muscles, or pulsation of the umbilical cord. N.M. Stat. Ann. §24-9A-1(H) (1991).

19. Some states also cover research on conceptuses that *will be* the subject of an abortion. Fla. Stat. Ann. §390.001 (West 1986); and Okla. Stat. Ann. tit. 63 §1-732 (West 1987). Arguably those statutes might apply to embryo research if there is a possibility that the embryo will be terminated at the end of the research (since that termination could be analogized to an abortion).
20. See Appendix A and Table I for information about the law.
21. La. Rev. Stat. Ann §9:121 *et. seq.* (West 1991); N.H. Rev. Stat. Ann. sec 168-B:15(II) (Comp. Supp. 1993); Me. Rev. Stat. tit. 22 §1593 (West 1992); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); Mich. Comp. Laws §§333.2685 to 2692 (West 1992); Minn. Stat. Ann. §145.421 (West 1989); N.D. Cent. Code §§14-02.2-01 to -02 (1991); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws. §§11-54-1 (Supp. 1993); Utah Code Ann. §76-7-310 (1990).
22. N.H. Rev. Stat. Ann. §168-b:15(II) (Cum. Supp. 1993).
23. Minn. Stat. Ann. §145.422 (West 1989).
24. Mich. Comp. Laws §333.2685 (West 1992).
25. Mich. Comp. Laws §333.2685 (West 1992); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993).
26. 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993).
27. Mass. Ann. Laws ch. 112 §12J(a)(1) (Law. Co-op 1991); Mich. Comp. Laws §333.2686 (West 1992); N.D. Cent. Code §14-02.2-01(3) (1991); R.I. Gen. Laws §11-54-19(b) (Supp. 1993).
28. N.H. Rev. Stat. Ann. §168-B:13 (Cum. Supp. 1993)
29. 18 Pa. Cons. Stat. Ann. §3213(e) (Purdon Supp. 1993).
30. La. Rev. Stat. Ann. §9:128 (West 1991).
31. *See, e.g.*, Ark. Code Ann. §23-86-118(d) (1987); Hawaii Rev. Stat. §432:1-604(6) (Supp. 1992); Ill. Rev. Stat. Ann. ch. 215 para. 5/356m(b)(1)(c); Md. Ann. Code art. 48a §§477EE(6), and 470W (1990).
32. La. Rev. Stat. Ann. §9:121 *et seq.* (West 1991).
33. *Id.*, §121.
34. *Id.*, §123. *See, id.*, §125 (an *in vitro* fertilized ovum is an entity separate from the medical facility housing it).

35. *Id.*, §124.
36. *Id.*
37. *Id.*, §122.
38. *Id.*
39. *Id.*, §129.
40. *Id.*, §126.
41. *Id.*
42. *Id.*, §130.
43. *Id.*
44. *Id.*
45. *Id.*, §131.
46. *Id.*, §127.
47. *Id.*, §132.
48. There is also a wealth of statutory law prohibiting commercialization of bodily materials that does not apply to *ex utero* embryos. Some statutes only forbid payment for *aborted* conceptuses. *See, e.g.*, Ky. Rev. Stat. §436.026 (1985); Mo. Ann. Stat. §188.036(5) (Vernon Supp. 1992); Ohio Rev. Code Ann. §2919.14 (Baldwin 1992); Okla. Stat. Ann. tit. 63 §1-735 (West 1984); Tenn. Code Ann. §39-15-208 (1991); and Wyo. Stat. §35-6-115 (1988). Some statutes forbid only payment for organs for transplantation in terms which do not apply to embryos or embryonic tissue. *See, e.g.*, Tenn. Code Ann. §68-30-40 (1992). Some forbid payment for body parts only if the removal occurred after the individual's death. *See, e.g.*, Hawaii Rev. Stat. §327-10(a) (Supp. 1991); Idaho Code §39-3411 (West Supp. 1992); N.D. Cent. Code §23-06.2-10 (1991).
49. D.C. Code Ann §6-2601 (1989); Fla. Stat. Ann. §873.05 (West Supp. 1992); Georgia Code Ann. §26-9957(a) (Harrison Supp. 1991) (except for health services education, *id.* at (b)(5)); Ill. Stat. Ann. ch. 110½ para. 308.1 (Smith-Hurd 1992); La. Rev. Stat. Ann. §9:122 (West Supp. 1993); Mich. Comp. Laws. Ann. §§333.2690 (West 1992); Minn. Stat. Ann. §145.422(3) (West 1989); 18 Pa. Cons. Stat. Ann. §3216(3) (Purdon Supp. 1992); R.I. Gen. Laws. §11-54-1 (Supp. 1993); Texas Penal Code §48.02 (1992); Utah Code Ann. §76-7-311 (1990); and Va. Code §32.1-289.1 (1991).
50. Me. Rev. Stat. Ann. tit. 22 §1593 (1992); Mass. Ann. Laws. ch. 112 §12(J)(a)(IV) (Lawyer's Co-op 1991); Mich. Comp. Laws §333.10204(1) (West Supp. 1992) and N.D. Cent. Code §14-02.2-02(4) (1991).

51. Cal. Penal Code §367f (West 1986); Cal. Health & Safety Code §7155 (West Supp. 1993); Conn. Gen. Stat. Ann. §19a-280(a) (West Supp. 1992); Del. Code Ann. tit. 16 §2713 (Supp. 1990); Nev. Rev. Stat. §201.460 (Michie Supp. 1991); Pa. tit. 35 §10025 (Purdon Supp. 1992).
52. N.Y. Public Health Law §4307 (McKinney 1985); W. Va. Code §16-19-7a (1991); and Wisc. Stat. Ann. §146.345 (West 1989).
53. *See, e.g.,* Gerald H. Zeilmaker *et al.*, "Two Pregnancies Following Transfer of Intact Frozen-Thawed Embryos," 42 *Fertility and Sterility* 293 (1984).
54. Pregnancies have been achieved after the donation of an embryo fertilized in vitro. *See, e.g.,* P. Lutjen, A. Trounson, J. Leeton, J. Findlay, C. Wood, and P. Renou, "The Establishment and Maintenance of Pregnancy Using In Vitro Fertilization and Embryo Donation in a Patient with Primary Ovarian Failure," 307 *Nature* 174 (1984).
55. 18 Pa. Cons. Stat. Ann. §3213(e) (Purdon Supp. 1993).
56. *See* note 31, *supra*.
57. Me. Rev. Stat. tit. 22 §1593 (West 1992); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); N.D. Cent Code §§14-02.2-01 to -02 (1991); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws. §11-54-1 (Supp. 1993). While by its terms the Utah statute seems to prohibit it (Utah Code Ann. §§76-7-310 (1990)), a court interpretation of the statute would appear to allow it. *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).
58. Me. Rev. Stat. tit. 22 §1593 (West 1992); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); N.H. Rev. Stat. Ann. Sec. 168-B:15(II) (Com. Supp. 1993); N.D. Cent Code §§14-02.2-01 to -02 (1991); R.I. Gen. Laws. §11-54-1 (Supp. 1993). While by its terms the Utah statute seems to prohibit it (Utah Code Ann. §§76-7-310 (1990)), a court interpretation of the statute would appear to allow it. *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).
59. La. Rev. Stat. Ann. §9:121 *et. seq.* (1991); Me. Rev. Stat. tit. 22 §1593 (West 1992); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); Minn. Stat. Ann. §145.422 (West 1989); N.D. Cent Code §§14-02.2-01 to -02 (1991); N.H. Rev. Stat. Ann. sec. 168-B:15(II) (Cum. Supp. 1993); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws. §11-54-1 (Supp. 1993). While by its terms the Utah statute seems to prohibit it (Utah Code Ann. §76-7-310 (1990)), a court interpretation of the statute would appear to allow it. *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).
60. In some cases, of course, the decisionmaker may be the pregnant woman alone—for example, if the couple break up during the pregnancy or if the woman has decided to be a single mother via artificial insemination by donor.
61. Embryo biopsy involves embryos created through *in vitro* fertilization and destined for implantation in a woman. One cell of an eight-cell embryo is removed, and the remaining seven cells frozen. Genetic screening is undertaken on the one cell and, if the tests are negative, the remaining seven cells are gestated to produce a child. At the eight-cell stage, all cells are totipotent and thus the embryo would develop normally, with no damage attributable

- to the removal of the one cell. For a description of the benefits of genetic screening of the embryo, see C. Grobstein, *From Chance to Purpose: An Appraisal of External Human Fertilization* 1, 123 (1981). See also J. Simpson and S. Carson, "Editorial: Preimplantation Genetic Diagnosis," 327 *New Eng. J. Med.* 951 (1992); A. H. Handyside *et. al.*, "Biopsy of Human Preimplantation Embryos and Sexing by DNA Amplification," 2 *Lancet* 347 (1989).
62. Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); Mich. Comp. Laws. §§333.2685 to 2692 (West 1992); N.H. Rev. Stat. Ann. sec 168-B:15(II) (Cu. Supp. 1993); N.D. Cent Code §§14-02.2-01 to -02 (1991); R.I. Gen. Laws. §11-54-1 (Supp. 1993); Utah Code Ann. §76-7-310 (1990).
  63. La. Rev. Stat. Ann. §9:121 *et. seq.* (West 1991); Me. Rev. Stat. tit. 22 §1593 (West 1992); Minn. Stat. Ann. §145.421 (West 1989); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993).
  64. Fla. Stat. Ann. §390.001 (West 1986); and Okla. Stat. Ann. tit. 63 §1-732 (West 1987) (defines abortion as "the purposeful termination of human pregnancy," *id.* §1-730 (1)).
  65. La. Rev. Stat. Ann. §9:121 *et. seq.* (West 1991) (so long as the embryo will be brought to term); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); Mich. Comp. Laws. §§333.2685 to 2692 (West 1992); Minn. Stat. Ann. §145.421 (West 1989); N.D. Cent Code §§14-02.2-01 to -02 (1991); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws. §11-54-1 (Supp. 1993). While the Utah statute (Utah Code Ann. §76-7-310 (1990)) would appear to forbid it, a court interpretation would appear to allow it. *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).
  66. Me. Rev. Stat. tit. 22 §1593 (West 1992); N.H. Rev. Stat. Ann. sec 168-B:15(II) (Cum. Supp. 1993).
  67. La. Rev. Stat. Ann. §9:121 *et. seq.* (West 1991); Me. Rev. Stat. tit. 22 §1593 (West 1992); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); Mich. Comp. Laws. §§333.2685 to 2692 (West 1992); Minn. Stat. Ann. §145.421 (West 1989); N.D. Cent Code §§14-02.2-01 to -02 (1991); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws. §11-54-1 (Supp. 1993); Utah Code Ann. §76-7-310 (1990).
  68. Biotechnology companies currently develop cell lines from fetuses. Sheehan, "Fetal Tissue Implants: An Explosive Technology Needs National Action," 92 *Dickinson L. R.* 895, 901 (1988).
  69. Minn. Stat. Ann. §145.1627(3) (West 1989).
  70. Nev. Rev. Stat. Ann. §451.015 (Michie 1991).
  71. See, e.g., C. Grobstein, *supra* note 61.
  72. *Research on the Fetus*, *infra* note 111, at 18. See also Vaheri, Vesikari, Oker-Blom, Seppula, Parkman, Veronelli & Robbins, *Isolation of Attenuated Rubella-Vaccine Virus From Human Products of Conception and Uterine Cervix*, 286 *New Eng. J. Med.* 1071 (1972). Questions have been raised about whether such a study was necessary or whether the findings could have

been made by a retrospective study of women who had erroneously been vaccinated during pregnancy. Such erroneous vaccinations did indeed occur. *See, e.g., Cooke, Critique of the Batelle Report*, in *Appendix: Research on the Fetus*, *infra* note 108, at 15-155, 15-157.

73. La. Rev. Stat. Ann. §9:121 *et. seq.* (West 1991); Me. Rev. Stat. tit. 22 §1593 (West 1992); Mass. Ann. Laws. ch. 112 §12J (Law. Co-op 1991); Mich. Comp. Laws. §§333.2685 to 2692 (West 1992); Minn. Stat. Ann. §145.421 (West 1989); N.D. Cent. Code §§14-02.2-01 to -02 (1991); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws. §11-54-1 (Supp. 1993); and Utah Code Ann. §76-7-310 (1990).
74. D.C. Code Ann. §6-2601 (1989); Fla. Stat. Ann. §873.05 (West Supp. 1992); Ga. Code Ann. §26-9957(a) (Harrison Supp. 1991) (except for health services education, *id.* at (b)(5)); Ill. Stat. Ann. ch. 110½ para. 308.1 (Smith-Hurd 1992); La. Rev. Stat. Ann. §9:122 (West Supp. 1993); Me. Rev. Stat. Ann. tit. 22 §1593 (1992); Mass. Ann. Laws ch. 112 §12(J)(a)(IV) (Lawy. Co-op 1991); Mich. Comp. Laws Ann. §§333.2690 (West 1992); Minn. Stat. Ann. §145.422(3) (West 1989); N.D. Cent. Code §14-02.2-02(4) (1991); 18 Pa. Cons. Stat. Ann. §3216(3) (Purdon Supp. 1992); R.I. Gen. Laws §11-54-1 (Supp. 1993); Texas Penal Code §48.02 (1992); Utah Code Ann. §76-7-311 (1990); Va. Code §32.1-289.1 (1991).
75. Cal. Penal Code §367f (West 1986); Cal. Health & Safety Code §7155 (West Supp. 1992); Conn. Gen. Stat. Ann. §19a-280(a) (West Supp. 1992); Del. Code Ann. tit. 16 §2713 (Supp. 1990); D.C. Code Ann. §6-2601 (1989); Fla. Stat. Ann. §873.05 (West Supp. 1992); Ga. Code Ann. §26-9957(a) (Harrison Supp. 1991) (except for health services education, *id.* at (b)(5)); Ill. Stat. Ann. ch. 110½ para. 308.1 (Smith-Hurd 1992); La. Rev. Stat. Ann. §9:122 (West Supp. 1993); Mich. Comp. Laws Ann. §333.2690 (West 1992); Minn. Stat. Ann. §145.422(3) (West 1989); Nev. Rev. Stat. §201.460 (Michie Supp. 1991); 18 Pa. Cons. Stat. Ann. §3216(3) (Purdon Supp. 1992); R.I. Gen. Laws §11-54-1 (Supp. 1993); Texas Penal Code §48.02 (1992); Utah Code Ann. §76-7-311 (1990); Va. Code §32.1-289.1 (1991). In addition, three other states' statutes ban payment for an enumerated list of body parts that does not include embryos or embryonic tissue but can be amended to include it by agency decision. N.Y. Pub. Health Law §4307 (McKinney 1985); W. Va. Code §16-19-7a (1991); Wisc. Stat. Ann. §146.345 (West 1989).
76. 735 F. Supp. 1361 (N.D. Ill. 1990).
77. *Id.* at 1377 (citations omitted). The court also held that the statute was impermissibly vague because of its failure to define "experiment" or "therapeutic." *Id.* at 1376.
78. *Id.* at 1364.
79. *Id.* at 1364-65.
80. *Id.* at 1364.
81. *Margaret S. v. Edwards*, 794 F.2d 994, 999 (5th Cir. 1986).
82. *Id.*



83. *Id.* A concurring judge found this analysis to be contrived and opined that the provision was not unconstitutionally vague. *Id.* at 1000 (Williams, J., concurring). Instead, he suggested that the prohibition was unconstitutional because “under the guise of police regulation the state has actually undertaken to discourage constitutionally privileged induced abortions.” *Id.* at 1002, citing *Thornburgh v. American College of Obstetricians and Gynecologists*, 106 S. Ct. 2169, 2178 (1986). The concurring judge pointed out that the state had “failed to establish that tissue derived from an induced abortion presents a greater threat to public health or other public concerns than the tissue of human corpses [upon which experimentation is allowed].” *Id.* Moreover, the state had not shown a rational justification for prohibiting experimentation on fetal tissue from an induced abortion, rather than a spontaneous one. *Id.*
84. *Margaret S. v. Edwards*, 794 F.2d 994, 999 (5th Cir. 1986).
85. *Id.*
86. 794 F. Supp. 1537 (D. Utah 1992).
87. *Id.* at 1550.
88. *Id.* at 1550.
89. Robertson, “The Scientist’s Right to Research: A Constitutional Analysis,” 51 *S. Cal. L. Rev.* 1203-79, 1213 (1977). Robertson argues that the right to participate as a research subject is protected by the fourteenth amendment’s right to privacy as recognized in *Roe v. Wade*, 410 U.S. 113 (1973). This right arises from an individual’s privacy interest in autonomous decision-making concerning the use of his or her body in an experiment designed to further medical knowledge or to be of personal benefit. *Id.*
90. *Id.* at 1212.
91. *Id.* at 1204.
92. *Meyer v. Nebraska*, 262 U.S. 390 (1923).
93. *Id.* at 399.
94. Robertson, *supra* note 89, at 1212 (the language of *Meyer* could be interpreted to support an individual’s right to help acquire knowledge by participating as an experimental subject).
95. *Id.*
96. *Id.* at 1253.
97. *Id.* at 1254.
98. *Id.* at 1256.
99. *Id.* at 1253.

100. The Nuremberg Code of Ethics in Medical Research provides that, to be ethical, an experiment "should be so designed and based on the results of animal experimentation ...." The Nuremberg Code is reprinted as Appendix B in Lori B. Andrews, *Medical Genetics: A Legal Frontier* 272-273 (1987).
101. Federal regulations governing fetal research require that appropriate animal studies be undertaken before human studies are done. 45 C.F.R. §46.202(a)(2) (1992).
102. N.M. Stat. Ann. §24-9A-5A (1) (1991).
103. Robertson, "The Law of Institutional Review Boards," 57 *U.C.L.A. L. Rev.* 484, 487 (1979); Barber, "The Ethics of Experimentation Upon Human Subjects," 234 *Sci. Am.* 25 (February 1976).
104. Mulford, "Experimentation on Human Beings," 20 *Stan. L. Rev.* 99, 108 (1967).
105. 45 C.F.R. §§46.101-46.409 (1992).
106. Mass. Ann. Laws ch. 112 sec 12J sec. 13J(a)(IV) (Law. Co-op 1991).
107. Gena Corea, *The Mother Machine* 102, 135 n.2 (1984).
108. Stephen Toulmin, "Fetal Experimentation: Moral Issues and Institutional Controls," in National Commission for the Protection on Human Subjects of Biomedical and Behavioral Research, *Appendix: Research on the Fetus* 10-11 (1975).
109. It has been charged that some abortionists performed abortion procedures that were more potentially harmful to the pregnant woman in order to obtain a live fetus for research purposes. Schulman, "Editorial: Major Surgery for Abortion and Sterilization," 40 *Obstet. Gynecol.* 738, 739 (1972).
110. See, e.g., "Fetal Experimentation" *supra* note 2 at 1202 (1974); P. Ramsey, *The Ethics of Fetal Research* 88-99 (1975).
111. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations: Research on the Fetus* (1975) (hereinafter, *Research on the Fetus*). This document is reprinted in 40 *Fed. Reg.* 33,530 (1975). See also Alexander Capron, "The Law Relating to Experimentation with the Fetus," 13-1 in *Appendix: Research on the Fetus, supra* note 108. "Such attempts to take away parental custody and control on the grounds that the mother has abandoned the fetus or is unable to take account of its interests seem unwise (because of the burden placed on state officials which they are ill-equipped to handle), misguided (because it is based on misapprehension of the significance of the decision to abort), unnecessary (because the interests of such fetuses are already protected by the law from parental abuse to the same degree as those of other children), and perhaps unconstitutional (because it chills exercise of the right to have an abortion and operates arbitrarily through presumptions rather than actual facts about parental choices)."
112. See, e.g., the American Fertility Society guidelines which provide that the couple should have primary decision-making authority with respect to the fate of their embryos. Ethics

Committee of the American Fertility Society, "Ethical Considerations of the New Reproductive Technologies," 53 *Fertility and Sterility* 60S (Supplement 2, June 1990).

113. For a discussion of the type of information that should be presented in advance of *in vitro* fertilization, see Andrews and Jaeger, Legal Aspects of Infertility," in M. Seibel, ed., *Infertility: A Comprehensive Text* (1989).
114. N.M. Stat. Ann. §24-9A-2(b) (1991).
115. Mass. Ann. Laws ch. 112 §12 J (Law. Co-op 1991); Mich. Comp. Laws §333.2686 (West 1992); Minn. Stat. Ann. §145.421 (West 1989); N.H. Rev. Stat. Ann. sec 168-B:15(II) (Cum. Supp. 1993); N.D. Cent. Code §14-02.2-01 (1991); 18 Pa. Cons. Stat. Ann. §3216 (Purdon Supp. 1993); R.I. Gen. Laws §11-54-1 (Supp. 1993). In Utah, that result is reached due to a federal case, *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).
116. 18 Pa. Cons. Stat. Ann. §3816 (Purdon Supp. 1993). A similar law was in effect in Illinois. Ill. Ann. Stat. ch. 38, para. 81-26(7) (Smith-Hurd Supp. 1989). That law was struck down as unconstitutional, though, because *inter alia*, it did not have exceptions for other infertility techniques or genetic screening techniques that were relevant to couples' reproductive decisionmaking. *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill.), *aff'd*, 914 F. 2d 260 (7th Cir. 1990), *cert. denied sub nom.*, *Scholberg v. Lifchez*, 498 U.S. 1069 (1991).
117. Utah Code Ann. §76-7-310 (1990).
118. Mass. Ann. Laws ch. 112 §12J (Lawyers Co-op 1991); Mich. Comp. Laws §§333.2685 to 2692 (West 1992); N.D. Cent. Code §§1402-02.2-01 to -02 (1991); R.I. Gen. Laws §11-54-1 (Supp. 1993).
119. Department of Health and Social Security, *Report of the Committee of Inquiry into Human Fertilization and Embryology* §11.22 at 66 (1984).
120. Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, *Report on the Disposition of Embryos Produced by In Vitro Fertilization* §3.29 at 47 (1984).
121. Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters* 216 (1985). However, the Commission noted that "[s]hould the state of medical knowledge at some future date indicate that the fourteen day period is inappropriate, by either being too short or too long, the regulations could easily be amended." *Id.*
122. See, e.g., "The Biologic Characteristics of the Preembryo," in Ethics Committee of the American Fertility Society, *Ethical Considerations of the New Reproductive Technologies* 53 *Fertility and Sterility* 34S-36S (1986).
123. As one commentator notes, sentience develops gradually, but fetuses generally have the capacity to feel pain sometime during the fifth month. M. Bayles, *Reproductive Ethics* 65 (1984).

124. Wilson, "A Report on Legal Issues Involved in Research on the Fetus," in *Appendix: Research on the Fetus*, *supra* note 108, 14-1, 14-18 to -19.
125. For example, the Arkansas fetal research law prohibits nontherapeutic research on an aborted fetus born alive (Ark. Stat. Ann. §20-17-802(b)(1) (1991)), but allows it on an aborted fetus born dead if the mother consents (§20-17-802(b)(2)). The Arkansas statute defines a "dead fetus" as "a product of human conception exclusive of its placenta or connective tissue, which has suffered death prior to its complete expulsion or extraction from the mother as established by the fact that, after the expulsion or extraction the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles." *Id.*, §20-17-801(b)(2). Thus it appears that *ex utero* fetuses in the earlier developmental stages are permissible subjects for research so long as the mother consents. Similarly, in California, nontherapeutic research on aborted fetuses is permissible if the fetus is "lifeless," which is defined to mean that the fetus has no discernible heartbeat. Cal. Health & Safety Code §25956(a) (West 1984). In addition, the New Mexico restriction on research only applies if the fetus exhibits either heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord. N.M. Stat. Ann. §24-9A-1(H) (1991).
126. Few of the embryo research laws address this issue. Ironically, in Michigan, the law has stronger prohibitions on research on embryos that will not go to term than those that will. Mich. Comp. Laws §333.2685 (West 1992).
127. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations: Research on the Fetus* 66-67 (1975). This document is reprinted in 40 *Fed. Reg.* 33,530 (1975).
128. 42 U.S.C.A. §289g(b) (West Supp. 1992).
129. Research on the Fetus, *supra* note 111, at 66-67. See also Lebacqz, "Reflections on the Report and Recommendations of the National Commission: Research on the Fetus," 22 *Vill. L. Rev.* 357, 359-360 (1977).
130. Research on the Fetus, *supra* note 111, at 67.
131. Lebacqz, *supra* note 129, at 361.
132. Mass. Ann. Laws ch. 112, §12J(a)(I) (Michie/Law. Co-op. 1991); Mich. Comp. Laws Ann. §333.2685(1) (West 1992); N.D. Cent. Code §14-02.2-01(1) (1991); and R.I. Gen. Laws §11-54-1(a) (Supp. 1993).
133. Minn. Stat. Ann. §145.422(2) (West 1989).
134. Vaheri, *et al.*, "Isolation of Attenuated Rubella-Vaccine Virus from Human Products of Conception and Uterine Cervix," 286 *New Eng. J. Med.* 1071 (1972). Questions have been raised about whether such a study was necessary or whether the findings could have been made by a retrospective study of women who had erroneously been vaccinated during pregnancy. Such erroneous vaccinations did indeed occur. See, e.g., Cooke, "Critique of the Batelle Report," in *Appendix: Research on the Fetus*, *supra* note 108, 15-155, 15-157.

135. The Use of Fetuses and Fetal Material for Research, Report of the Advisory Group, Dept. of Health and Social Security, Scottish Home and Health Dept., Welsh Office, London (1972) at 12, cited in "Fetal Research," *supra* note 111, at 141 n.74.
136. 45 C.F.R. §46.203(c)(1992)
137. *Margaret S. v. Edwards*, 794 F. 2d 994, 998-99 (5th Cir. 1986); *Lifchez v. Hartigan*, 735 F. Supp. 260 (7th Cir. 1990), *cert. denied sub nom.*, *Scholberg v. Lifchez*, 498 U.S. 1069 (1991). *But see Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).
138. *See, e.g.*, Cal. Bus. & Prof. Code §2254 (West Supp. 1994), Health & Safety Code §25956(b) (West 1984).
139. *See, e.g.*, N.M. Stat. Ann. §24-9A-6 (1991), providing for imprisonment for up to one year or the payment of a fine up to \$1,000 or both.
140. Mass. Ann. Laws ch. 112, §12J(a)(VI) (Law. Co-op. 1991). An Institutional Review Board's reasonable, well-documented written approval provides a complete defense to criminal prosecution of the researcher. *Id.*
141. *Id.*, §12J(b)(I).
142. *Id.*, §12J(b)(III).
143. *Id.*, §12J(b)(VI).
144. *Id.*, §12J(b)(VII).
145. *Id.*, §12J(b)(VIII).

TABLE I  
STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos For		
		Cyropreservation	Preimplantation screening	Gene Therapy	Cell Line Development	Twinning	Basic Research	Any Purpose	Research	Transplantation
Alabama										
Alaska										
Arizona										
Arkansas										
California										X
Colorado										
Connecticut										X

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STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos For		
		Cryopreservation	Preimplantation screening	Gene Therapy	Cell Line Development	Twinning	Basic Research	Any Purpose	Research	Transplantation
Delaware										X
District of Columbia								X		
Florida								X		
Georgia								X <sup>1</sup>		
Hawaii										
Idaho										
Illinois								X		

TABLE I  
STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos For		
		Cryopreservation	Preimplantation screening	Gene Therapy	Cell Line Development	Twinning	Basic Research	Any Purpose	Research	Transplantation
Indiana										
Iowa										
Kansas										
Kentucky										
Louisiana	X		X		X	X	X	X		
Maine	X	X	X	X	X	X	X		X	
Maryland										



TABLE I  
STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos For		
		Cryopreservation	Precimplantation screening	Gene Therapy	Cell Line Development	Twining	Basic Research	Any Purpose	Research	Transplantation
Massachusetts	X	X			X	X	X		X	
Michigan	X				X		X	X <sup>2</sup>	X	
Minnesota	X		X		X	X	X	X		X <sup>1</sup>
Mississippi										
Missouri										
Montana										
Nebraska										

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STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos For		
		Cyropreservation	Preimplantation screening	Gene Therapy	Cell Line Development	Twinning	Basic Research	Any Purpose	Research	Transplantation
Nevada										X
New Hampshire	X		X	X		X				
New Jersey										
New Mexico										
New York										X'
North Carolina										
North Dakota	X	X			X	X	X		X	



TABLE I  
STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos For		
		Cryopreservation	Preimplantation screening	Gene Therapy	Cell Line Development	Twinning	Basic Research	Any Purpose	Research	Transplantation
Tennessee										
Texas								X		
Utah	X				X		X	X		
Vermont										
Virginia								X		
Washington										
West Virginia										X'

TABLE 1  
STATE LAWS ON EMBRYO RESEARCH AND COMMERCIALIZATION

State	Prohibits certain types of embryo research	Potentially Prohibits						Prohibits Payment For Embryos for		
		Cryopreservation	Preimplantation screening	Gene Therapy	Cell Line Development	Twinning	Basic Research	Any Purpose	Research	Transplantation
Wisconsin										X <sup>2</sup>
Wyoming										

1. Except for health services education.
2. List of body parts that may not be sold may be expanded by administrative action to include embryo or embryonic parts.
3. Permits cell line sale.

## **Appendix A**

### **State-by-State Description of Laws**

## APPENDIX A

### STATE-BY-STATE DESCRIPTION OF EMBRYO RESEARCH LAWS

#### LOUSIANA

Is there a statute potentially affecting embryo research? Yes,  
La. Rev. Stat. Ann. secs., 9:121-133 (West 1991)

The Lousiana statute is extremely restrictive of embryo research. It provides that, "The use of a human ovum fertilized in vitro is solely for the support and contribution of the complete development of human in utero implantation. No in vitro fertilized human ovum will be farmed or cultured solely for research purposes or any other purposes." sec. 122.

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

No.

Stage of development of the embryo?

It applies only to in vitro embryos.

Distinctions based on whether it is intended that the embryo go to term?

Yes. The only allowable use of embryos is for implantation.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Qualifications of the health care provider?

"Only medical facilities meeting the standards of the American Fertility Society and the American College of Obstetricians and Gynecologists and directed by a medical doctor licensed to practice medicine in this state and possessing specialized training and skill in in vitro fertilization also in conformity with the standards established by the American Fertility Society or the American College of Obstetricians and Gynecologists shall cause the in vitro fertilization of a human ovum to occur." sec. 128.

Liability standards?

The statute provides for certain immunities from liability with respect to lawsuits brought on behalf of the embryo. It provides that "Strict liability or liability of any kind including actions relating to succession rights and inheritance shall not be applicable to any physician, hospital, in vitro fertilization clinic, or their agent who acts in good faith in the screening, collection, conservation, preparation, transfer, or cryopreservation of the human ovum fertilized in vitro for transfer to the human uterus. Any immunity granted by this section is applicable only to an action brought on behalf of the in vitro fertilized human ovum as a juridical person." sec. 132

Does the statute potentially prohibit...

Embryo cryopreservation?

No. The statute seems to anticipate that cryopreservation will be used. sec. 129.

Embryo donation?

No. In fact, the statute specifically seems to require donation in certain circumstances. It provides that "If the in vitro fertilization patients fail to express their identify, then the physician shall be deemed to be temporary guardian of the in vitro fertilized human ovum until adoptive implantation can occur." sec. 126.

Preimplantation genetic screening?

Yes. The statute says that the embryo must be used "solely for the support and contribution of the complete development of human in utero implantation." sec. 122. In addition, embryos may not be intentionally destroyed. sec. 129. Since some embryos will not be implanted, depending on the results of the preimplantation



screening, the use of the technology appears not to be permissible.

Gene therapy or other treatment for embryos?

No, so long as embryo will be brought to term.

Cell line development?

Yes.

Twinning?

Yes.

Basic scientific research?

Yes.

MAINE

Is there a statute potentially affecting embryo research? Yes,  
Me. Rev. Stat. Ann. tit. 22 sec. 1593 (West 1992)

The Maine statute prohibits using any live human  
extrauterine fetus for any form of experimentation. sec. 1593.

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such  
as genetic diagnostic services or in vitro fertilization?

No.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go  
to term?

No.

Distinctions based on the level of risk to the embryo or  
resulting child?

No.

Does the statute potentially prohibit...

Embryo cryopreservation?

Yes.

## CHAPTER 3. HUMAN EMBRYOS

### Section

- 121. Human embryo; definition.
- 122. Uses of human embryo in vitro.
- 123. Capacity.
- 124. Legal status.
- 125. Separate entity.
- 126. Ownership.
- 127. Responsibility.
- 128. Qualifications.
- 129. Destruction.
- 130. Duties of donors.
- 131. Judicial standard.
- 132. Liability.
- 133. Inheritance rights.

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### § 121. Human embryo; definition

A "human embryo" for the purposes of this Chapter is an in vitro fertilized human ovum, with certain rights granted by law, composed of one or more living human cells and human genetic material so unified and organized that it will develop in utero into an unborn child.

Added by Acts 1986, No. 964, § 1.

### Historical and Statutory Notes

In this section as enacted in 1986, quotation marks were inserted around "human embryo" on authority of R.S. 24:253.

#### Title of Act:

An Act to enact Chapter 3 of Code Title I of Code Book I of Title 9 of the Louisiana Revised

Statutes of 1950, to be comprised of R.S. 9:121 through 133, relative to in vitro fertilized ovum; to provide for the definition, capacity, legal status, ownership and the inheritance rights of human embryos; and to provide for related matters. Acts 1986, No. 964.

### Law Review Commentaries

The legal status of the embryo. Lori B. Andrews, 32 Loyola (La.) L.Rev. 357 (1986).

## MASSACHUSETTS

Is there a statute potentially affecting embryo research? Yes, 4  
Mass. Ann. Laws ch. 112 sec. 12 J (Law. Co-op 1991).

The Massachusetts statute provides that "No person shall use any live human fetus whether before or after expulsion from its mother's womb, for scientific, laboratory research or other kind of experimentation." sec. 12 J(a)(1). There is an exception for "diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus involved or the mother involved." sec. 12 J(a)(1).

A different subsection of section 12 J (prohibiting the sale or transfer of a fetus for experimentation) states that "[f]or purposes of this section, the word 'fetus' shall include also an embryo or neonate.

The Massachusetts statute provides an elaborate regulatory mechanism. Implicitly, an Institutional Review Board must approve the research. The statute provides that, in any prosecution for violating the law, it is a complete defense that the procedure had written IRB approval. sec. 12 J(a)(IV). IRB approvals and research protocols must be filed with the office of the district attorney in the county in which the research institution is located. Id. If the District Attorney disagrees with the IRB and believes that the proposed research violates the statute, he or she may file a complaint in court against the people who are performing (or intend to perform) the research. sec. 12J(b)(I).

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

Yes.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

Yes, diagnostic and remedial procedures are permissible.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Does the statute potentially prohibit...

Embryo cryopreservation?

Yes.

Embryo donation?

Yes.

Preimplantation genetic screening?

No.

Gene therapy or other treatment for embryos?

No.

Cell line development?

Yes.

Twinning?

Yes.

Basic scientific research?

Yes.

## MICHIGAN

Is there a statute potentially affecting embryo research? Yes,  
Mich. Comp. Laws sec. 333.2685 (West 1992).

The Michigan law prohibits the "use of a live human embryo...for nontherapeutic research if, in the best judgment of the person conducting the research, based upon the available knowledge or information at the approximate time of the reserach, the research substantially jeopardizes the life or health of the embryo.... Nontherapeutic research shall not in any case be performed on an embryo... known to be the subject of a planned abortion being performed for any purpose other than to protect the life of the mother." sec. 333.2685. Nontherapeutic research is defined as "scientific or laboratory research, or other kind of experimentation or investigation not designed to improve the health of the research subject." sec. 333.2692.

An embryo is considered to be live under the terms of the statute if it shows evidence of life as determined by the same medical standards as are used in determining life in a spontaneously aborted embryo at approximately the same stage of gestational development. sec. 333.2687. This definition is confusing with respect to an in vitro embryo which, unlike a spontaneously aborted embryo of that stage of development, could be expected to develop and potentially turn into a child. Because it seems contrary to consider the in vitro embryo not to be alive, the statute is analyzed with the presumption that its reach extends to in vitro embryos.

The statute has an exception for "diagnostic, assessment, or treatment procedures, the purpose of which is to determine the life or status or improve the health of the embryo...involved or the mother involved." sec. 333.2686.

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

Yes, diagnostic and treatment procedures are permissible.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go to term?

Yes. Oddly the statute is more restrictive of research on embryos to be aborted.

Distinctions based on the level of risk to the embryo or resulting child?

Yes, research is prohibited if it "substantially jeopardizes" the life or health of the embryo.

Does the statute potentially prohibit...

Embryo cryopreservation?

No, so long as it does not substantially jeopardize the life or health of the embryo.

Embryo donation?

No, so long as it does not substantially jeopardize the life or health of the embryo.

Preimplantation genetic screening?

No.

Gene therapy or other treatment for embryos?

No, so long as it is considered therapeutic to the embryo or for the purpose of improving the health of the embryo.

Cell line development?

Yes, since this would presumably be nontherapeutic and inconsistent with further development of the embryo.

Twinning?

No, so long as it is considered therapeutic to the embryo or for the purpose of improving the health of the embryo.

Basic scientific research?

Yes, if the research substantially jeopardizes the life or health of the embryo.



**§ 12J. Experimentation on human fetuses prohibited; medical procedures authorized; consent; approval; civil and criminal liability and proceedings; severability**

(a) I. No person shall use any live human fetus whether before or after expulsion from its mother's womb, for scientific, laboratory, research or other kind of experimentation. This section shall not prohibit procedures incident to the study of a human fetus while it is in its mother's womb, provided that in the best medical judgment of the physician, made at the time of the study, said procedures do not substantially jeopardize the life or health of the fetus, and provided said fetus is not the subject of a planned abortion. In any criminal proceeding a fetus shall be conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the study, that she was not planning an abortion.

This section shall not prohibit or regulate diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus involved or to preserve the life or health of the fetus involved or the mother involved.

A fetus is a live fetus for purposes of this section when, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development.

(a) II. No experimentation may knowingly be performed upon a dead fetus unless the consent of the mother has first been obtained, provided, however, that such consent shall not be required in the case of a routine pathological study. In any criminal proceeding, consent shall be conclusively presumed to have been granted for the purposes of this section by a written statement, signed by the mother who is at least eighteen years of age, to the effect that she consents to the use of her fetus for scientific, laboratory, research or other kind of experimentation or study;

No.

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

Yes, harmless research is permitted.

Does the statute potentially prohibit...

Embryo cryopreservation?

No, not if it is viewed as harmless.

Embryo donation?

No, not if it is viewed as harmless.

Preimplantation genetic screening?

Yes, since it is not done to protect the life or health of the embryo and, since the embryo may be terminated, it is not harmless to the embryo.

Gene therapy or other treatment for embryos?

No, since it is designed to protect the health or life of the embryo.

Cell line development?

Yes, since this would probably be seen as harmful to the embryo.

Twinning?

Yes, unless it were viewed as harmless.

Basic scientific research?

Yes, unless harmless to the embryo.

NEW HAMPSHIRE

Statute potentially affecting embryo research? Yes, N.H. Rev. Stat. Ann. sec. 168-B:15(II) (1993 Cum. Supp.).

The statute provides that embryos donated for research purposes may not be transferred to a uterine cavity.

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

No.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Does the statute potentially prohibit...

Embryo cryopreservation?

No, the statute says that no embryo may be maintained ex utero in the non-cryopreserved state beyond 14 days. This would seem to envision cryopreservation.

Embryo donation?

Yes.

Preimplantation genetic screening?

Yes.

Gene therapy or other treatment for embryos?

Yes.

Twinning?

Yes.

Cell line development?

No.

Basic scientific research?

No, the statute says that no embryo donated for research may be transferred to a uterine cavity.

NORTH DAKOTA

Is there a statute potentially affecting embryo research? Yes,  
N.D. Cent. Code sec. 14-02.2-01 (1991).

The North Dakota statute prohibits using "any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory research, or other kind of experimentation." sec. 14-02.2-01(1). The law defines a live fetus as one that "shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development." sec. 14-02.2-01(4). Although the definition of live appears to cover only later-stage fetuses, it would seem contrary to common sense not to think of the embryo as "live," and thus the statute could be interpreted to apply to embryos. The next section of the statute (prohibiting the sale or stransfer of a fetus for experimentation) specifically states that "for purposes of this section, the word 'fetus' includes also an embryo..." sec. 14-02.2-02(4).

There is an exception for "diagnostic or remedial procedures the purpose of which is to determine or to preserve the life or health of the fetus involved or the mother involved." sec. 14-02.2-01(3)

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

Yes, there is an exception for diagnostic or remedial procedures. Stage of development of the embryo?

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Does the statute potentially prohibit...

Embryo cryopreservation?

Yes.

Embryo donation?

Yes.

Preimplantation genetic screening?

No.

Gene therapy or other treatment for embryos?

No.

Cell line development?

Yes.

Twinning?

Yes.

Basic scientific research?

Yes.

## PENNSYLVANIA

Is there a statute potentially affecting embryo research? Yes,  
18 Pa. Cons. Stat. Ann. sec. 3216 (Purdon Supp. 1993).

The Pennsylvania statute prohibits the performance of any nontherapeutic experimentation or nontherapeutic medical procedure upon any unborn child. sec. 3216(a). "Nontherapeutic" is defined as not intended to preserve the life or health of the child upon whom it is performed. Id. Unborn child is defined to cover the period from fertilization to birth. sec. 3203.

The statute provides exceptions for diagnostic tests for the unborn child in utero and in vitro fertilization and accompanying embryo transfer. sec. 3216(c).

The statute also sets out an informed consent requirement for the conduct of research on fetal tissue or organs. Written consent of the mother must be obtained. sec. 3216(b)(1).

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

Yes.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

Yes, for in vitro fertilization and for therapeutic procedures.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Does the statute potentially prohibit...

Embryo cryopreservation?

Yes, if viewed as nontherapeutic.

Embryo donation?

No.

Preimplantation genetic screening?

Yes, since it would be considered nontherapeutic.

Gene therapy or other treatment for embryos?

No, if it is considered therapeutic.

Cell line development?

Yes, since it would not be viewed as therapeutic.

Twinning?

Yes, unless it were viewed as harmless.

Basic scientific research?

Yes.



RHODE ISLAND

Is there a statute potentially affecting embryo research? R.I. Gen. Laws sec. 11-54-1 (Supp. 1993).

The Rhode Island statute prohibits use of "any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory research, or other kind of experimentation." sec. 11-54-1(a). The law defines a live fetus as one that "shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development." sec. 11-54-1(c). Although the definition of live appears to cover only later-stage fetuses, it would seem contrary to common sense not to think of the embryo as "live," and thus the statute could be interpreted to apply to embryos.

There is an exception for "diagnostic or remedial procedures the purpose of which is to determine or to preserve the life or health of the fetus involved or the mother involved." sec. 11-54-1(b).

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

Yes, for diagnostic or remedial procedures.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Does the statute potentially prohibit...

Embryo cryopreservation?

Yes.

Embryo donation?

Yes.

Preimplantation genetic screening?

No.

Gene therapy or other treatment for embryos?

No.

Cell line development?

Yes.

Twinning?

Yes.

Basic scientific research?

Yes.

UTAH

Is there a statute potentially affecting embryo research? Utah Code Ann. sec. 76-7-310 (1990).

The Utah statute provides that "Live unborn children may not be used for experimentation, but when advisable, in the best medical judgment of the physician, may be tested for genetic defects." sec. 76-7-310.

The reach of the statute, however, has been narrowed considerably by judicial interpretation. In Jane L. v. Bangerter, 794 F. Supp. 1537 (D. Utah 1992), the court held that the statute did not prohibit research that was intended to benefit the woman or the unborn child. Rather, the statute only prohibited research "designed solely to increase a researcher's knowledge and not intended to provide any therapeutic benefit to the mother or child." Id. at 1550.

Does the statute mention:

The need for appropriate previous animal research?

No.

Advance review?

No.

Consent to research?

No.

Exceptions for research for particular enumerated purposes such as genetic diagnostic services or in vitro fertilization?

Such exceptions have been created by the court.

Stage of development of the embryo?

No.

Distinctions based on whether it is intended that the embryo go to term?

No.

Distinctions based on the level of risk to the embryo or resulting child?

No.

Does the statute potentially cover...

Embryo cryopreservation?

No, due to the court's interpretation.

Embryo donation?

No, due to the court's interpretation.

Preimplantation genetic screening?

No.

Gene therapy or other treatment for embryos?

No, due to the court's interpretation.

Cell line development?

Yes.

Twinning?

No, due to the court's interpretation.

Basic scientific research?

Yes.

**Appendix B**

**Excerpts of State Laws**

## CHAPTER 3. HUMAN EMBRYOS

### Section

- 121. Human embryo; definition.
- 122. Uses of human embryo in vitro.
- 123. Capacity.
- 124. Legal status.
- 125. Separate entity.
- 126. Ownership.
- 127. Responsibility.
- 128. Qualifications.
- 129. Destruction.
- 130. Duties of donors.
- 131. Judicial standard.
- 132. Liability.
- 133. Inheritance rights.

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---

### § 121. Human embryo; definition

A "human embryo" for the purposes of this Chapter is an in vitro fertilized human ovum, with certain rights granted by law, composed of one or more living human cells and human genetic material so unified and organized that it will develop in utero into an unborn child.

Added by Acts 1986, No. 964, § 1.

### Historical and Statutory Notes

In this section as enacted in 1986, quotation marks were inserted around "human embryo" on authority of R.S. 24:253.

#### Title of Act:

An Act to enact Chapter 3 of Code Title I of Code Book I of Title 9 of the Louisiana Revised

Statutes of 1950, to be comprised of R.S. 9:121 through 133, relative to in vitro fertilized ovum; to provide for the definition, capacity, legal status, ownership and the inheritance rights of human embryos; and to provide for related matters. Acts 1986, No. 964.

### Law Review Commentaries

The legal status of the embryo. Lori B. Andrews, 32 Loyola (La.) L.Rev. 357 (1986).

## Library References

Infants ⇨1.  
WESTLAW Topic No. 211.

C.J.S. Infants §§ 2 to 4.  
Words and Phrases (Perm.Ed.)

**§ 122. Uses of human embryo in vitro**

The use of a human ovum fertilized in vitro is solely for the support and contribution of the complete development of human in utero implantation. No in vitro fertilized human ovum will be farmed or cultured solely for research purposes or any other purposes. The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited.

Added by Acts 1986, No. 964, § 1.

**§ 123. Capacity**

An in vitro fertilized human ovum exists as a juridical person until such time as the in vitro fertilized ovum is implanted in the womb; or at any other time when rights attach to an unborn child in accordance with law.

Added by Acts 1986, No. 964, § 1.

## Cross References

Unborn child, see C.C. art. 26.

**§ 124. Legal status**

As a juridical person, the in vitro fertilized human ovum shall be given an identification by the medical facility for use within the medical facility which entitles such ovum to sue or be sued. The confidentiality of the in vitro fertilization patient shall be maintained.

Added by Acts 1986, No. 964, § 1.

## Library References

Action ⇨13.  
WESTLAW Topic No. 13.  
C.J.S. Actions §§ 57 to 63.

**§ 125. Separate entity**

An in vitro fertilized human ovum as a juridical person is recognized as a separate entity apart from the medical facility or clinic where it is housed or stored.

Added by Acts 1986, No. 964, § 1.

**§ 126. Ownership**

An in vitro fertilized human ovum is a biological human being which is not the property of the physician which acts as an agent of fertilization, or the facility which employs him or the donors of the sperm and ovum. If the in vitro fertilization patients express their identity, then their rights as parents as

**HUMAN EMBRYOS**  
**Ch. 3**

**R.S. 9:129**

provided under the Louisiana Civil Code will be preserved. If the in vitro fertilization patients fail to express their identity, then the physician shall be deemed to be temporary guardian of the in vitro fertilized human ovum until adoptive implantation can occur. A court in the parish where the in vitro fertilized ovum is located may appoint a curator, upon motion of the in vitro fertilization patients, their heirs, or physicians who caused in vitro fertilization to be performed, to protect the in vitro fertilized human ovum's rights.

Added by Acts 1986, No. 964, § 1.

**Cross References**

Duties and rights of parents and children, see C.C. art. 215 et seq.

**Library References**

Guardian and Ward ⌘13(6).  
Parent and Child ⌘1.  
WESTLAW Topic Nos. 196, 285.

C.J.S. Guardian and Ward § 28.  
C.J.S. Parent and Child §§ 2 to 10.

**§ 127. Responsibility**

Any physician or medical facility who causes in vitro fertilization of a human ovum in vitro will be directly responsible for the in vitro safekeeping of the fertilized ovum.

Added by Acts 1986, No. 964, § 1.

**Library References**

Physicians and Surgeons ⌘10.  
WESTLAW Topic No. 299.

C.J.S. Physicians, Surgeons, and Other  
Health-Care Providers §§ 53, 57.

**§ 128. Qualifications**

Only medical facilities meeting the standards of the American Fertility Society and the American College of Obstetricians and Gynecologists and directed by a medical doctor licensed to practice medicine in this state and possessing specialized training and skill in in vitro fertilization also in conformity with the standards established by the American Fertility Society or the American College of Obstetricians and Gynecologists shall cause the in vitro fertilization of a human ovum to occur. No person shall engage in in vitro fertilization procedures unless qualified as provided in this Section.

Added by Acts 1986, No. 964, § 1.

**§ 129. Destruction**

A viable in vitro fertilized human ovum is a juridical person which shall not be intentionally destroyed by any natural or other juridical person or through the actions of any other such person. An in vitro fertilized human ovum that fails to develop further over a thirty-six hour period except when the embryo is in a state of cryopreservation, is considered non-viable and is not considered a juridical person.

Added by Acts 1986, No. 964, § 1.



## Historical and Statutory Notes

In the second sentence of this section as enacted in 1986, the spelling of "juridicial" was changed to "juridical" on authority of R.S. 24:253.

**§ 130. Duties of donors**

An in vitro fertilized human ovum is a juridical person which cannot be owned by the in vitro fertilization patients who owe it a high duty of care and prudent administration. If the in vitro fertilization patients renounce, by notarial act, their parental rights for in utero implantation, then the in vitro fertilized human ovum shall be available for adoptive implantation in accordance with written procedures of the facility where it is housed or stored. The in vitro fertilization patients may renounce their parental rights in favor of another married couple, but only if the other couple is willing and able to receive the in vitro fertilized ovum. No compensation shall be paid or received by either couple to renounce parental rights. Constructive fulfillment of the statutory provisions for adoption in this state shall occur when a married couple executes a notarial act of adoption of the in vitro fertilized ovum and birth occurs.

Added by Acts 1986, No. 964, § 1.

**§ 131. Judicial standard**

In disputes arising between any parties regarding the in vitro fertilized ovum, the judicial standard for resolving such disputes is to be in the best interest of the in vitro fertilized ovum.

Added by Acts 1986, No. 964, § 1.

**§ 132. Liability**

Strict liability or liability of any kind including actions relating to succession rights and inheritance shall not be applicable to any physician, hospital, in vitro fertilization clinic, or their agent who acts in good faith in the screening, collection, conservation, preparation, transfer, or cryopreservation of the human ovum fertilized in vitro for transfer to the human uterus. Any immunity granted by this Section is applicable only to an action brought on behalf of the in vitro fertilized human ovum as a juridical person.

Added by Acts 1986, No. 964, § 1.

## Library References

Hospitals ⇨7.  
Physicians and Surgeons ⇨16.  
WESTLAW Topic Nos. 204, 299.  
C.J.S. Hospitals § 8.

C.J.S. Physicians, Surgeons, and Other  
Health-Care Providers §§ 70, 81 to 86, 97  
to 102.

**§ 133. Inheritance rights**

Inheritance rights will not flow to the in vitro fertilized ovum as a juridical person, unless the in vitro fertilized ovum develops into an unborn child that is born in a live birth, or at any other time when rights attach to an unborn

**HUMAN EMBRYOS**  
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child in accordance with law. As a juridical person, the embryo or child born as a result of in vitro fertilization and in vitro fertilized ovum donation to another couple does not retain its inheritance rights from the in vitro fertilization patients.

Added by Acts 1986, No. 964, § 1.

**Historical and Statutory Notes**

In the second sentence of this section as changed to "juridical" on authority of R.S. enacted in 1986, the spelling of "juridicial" was 24:253.

**Cross References**

Successions, capacity of unborn child, see C.C. art. 954.

**Library References**

Descent and Distribution ¶25.

WESTLAW Topic No. 124.

C.J.S. Descent and Distribution § 27.

**CODE TITLE II—OF DOMICILE AND THE MANNER OF  
CHANGING THE SAME [BLANK]**

R.C.C. Articles 38 to 46.

**R.S. 40:1299.35.12**

**Note 2**

informed consent requirements in event that pregnancy creates emergency need for abortion because continuation of pregnancy poses immediate threat and grave risk to life or permanent physical health of pregnant woman did not provide for a suspension of requirement in case of "psychiatric emergency" consti-

tuted de minimis burden on abortion right in view of fact that statute does not prevent woman from seeking abortion; rather it insures that abortion decision is intelligently made in furtherance of legitimate state interest. *Margaret S. v. Treen*, D.C.1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

**MISCELLANEOUS HEALTH PROVISIONS**

**Ch. 5**

**§ 1299.35.13. Experimentation**

No person shall experiment on an unborn child or on a child born as the result of an abortion, whether the unborn child or child is alive or dead, unless the experimentation is therapeutic to the unborn child or child.

Added by Acts 1978, No. 435, § 1. Amended by Acts 1981, No. 774, § 1, eff. July 23, 1981.

**Validity**

*This section was held unconstitutional in Margaret S. v. Edwards, 794 F.2d 994 (5th Cir.1986). See Notes of Decisions, post.*

**Historical and Statutory Notes**

The 1981 amendment rewrote the section which previously read:

"No person shall experiment upon or sell a live child or unborn child unless such experimentation is therapeutic to the child or unborn child."

Pursuant to the statutory revision authority of the Louisiana State Law Institute, "an" was substituted for "a" preceding "unborn" in the section as amended in 1981.

**Cross References**

Crime of human experimentation, see R.S. 14:87.2.

**Law Review Commentaries**

Alternative means of reproduction: Virgin territory for legislation. Kathryn Venturatos Lorio, 44 La.L.Rev. 1641 (1984).

**Notes of Decisions**

**Vagueness, validity 2**

**Validity 1, 2**

**In general 1**

**Vagueness 2**

**1. Validity—In general**

State criminal statute, which prohibited any party from "experimenting" on unborn child or child born as result of abortion, was unconstitutionally vague; statute did not distinguish between medical experiments and medical tests. *Margaret S. v. Edwards*, C.A.5 (La.) 1986, 794 F.2d 994.

This section, prohibiting experimentation on unborn child or child born as result of abortion, except for therapeutic purposes, would substantially burden right of women in Louisiana to choose to terminate their pregnancies

by preventing examination of fetal tissue to diagnose possible infections or illnesses in women who have undergone abortions; statute could not stand with respect to either first trimester or second trimester abortions in that it did not serve state's legitimate interest during second trimester of protecting pregnant woman's health. *Margaret S. v. Treen*, D.C. 1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

Prevention of fetal research by Louisiana physicians which would result from this section's prohibiting enforcement of experimentation on aborted fetuses was not justified by any legitimate state interest furthered by the statute. *Margaret S. v. Treen*, D.C.1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

Provision of R.S. 40:1299.35.13 prohibiting experimentation on aborted fetuses violates equal protection clause by infringing on rights

## ABORTION

### Part 18

## R.S. 40:1299.35.14

### Note 1

of physicians to participate in fetal research without bearing rational relationship to achievement of legitimate state interest. *Margaret S. v. Treen*, D.C.1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

#### 2. — Vagueness, validity

Term "unborn child" as used in statute prohibiting experimentation, except for therapeutic purposes, "on an unborn child or on a child born as a result of an abortion" is unconstitutionally vague because it is impossible for pa-

thologist or other physician to distinguish or separate fetal tissue from maternal tissue in handling and treatment of tissue which is result of abortion and term "born as a result of abortion" is unconstitutionally vague because it is impossible for pathologist or other physician to distinguish tissue which is product of induced abortion from that which is product of spontaneous abortion and, therefore, section prohibiting such experimentation is void for vagueness. *Margaret S. v. Treen*, D.C.1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

### § 1299.35.14. Disposal of remains

A. Each physician who performs or induces an abortion which does not result in a live birth shall insure that the remains of the child are disposed of in accordance with rules and regulations which shall be adopted by the Department of Health and Human Resources.

B. The provisions of this Section shall not apply to, and shall not preclude, instances in which the remains of the child are provided for in accordance with the provisions of R.S. 8:651 et seq.

C. The attending physician shall inform each woman upon whom he performs or induces an abortion of the provisions of this Section within twenty-four hours after the abortion is performed or induced.

Added by Acts 1978, No. 435, § 1. Amended by Acts 1980, No. 418, § 1; Acts 1981, No. 774, § 1, eff. July 23, 1981.

#### Validity

*This section was held unconstitutional in Margaret S. v. Edwards, 794 F.2d 994 (5th Cir.1986). See Notes of Decisions, post.*

#### Historical and Statutory Notes

Pursuant to the statutory revision authority of the Louisiana State Law Institute, "or" was changed to "of" in the section heading.

The 1980 amendment rewrote this section, which had read:

"Any physician who shall perform or induce an abortion upon a pregnant woman shall in-

sure that the remains of the unborn child are disposed of in a manner consistent with the disposal of other human remains as provided by R.S. 8:651 through 8:662."

The 1981 amendment, in subsec. A and B, deleted "unborn" preceding "child"; in subsec. A, substituted "disposed of" for "cremated"; and added subsec. C.

#### Notes of Decisions

##### Physician-patient relationship 2

##### Validity 1

##### 1. Validity

State statute which required physician, within 24 hours of performing abortion, to "personally" inform patient of her right to have fetus cremated, buried, or disposed of as waste tissue violated patient's constitutional rights. *Margaret S. v. Edwards*, C.A.5 (La.) 1986, 794 F.2d 994.

Requirement in R.S. 40:1299.35.14, that physician tell woman she must choose between burial and other means of disposal of aborted fetus constitutes direct and undue burden on woman's constitutionally protected right to obtain an abortion. *Margaret S. v. Treen*, D.C. 1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

This section, stating that a physician who performed an abortion should insure that the remains of the unborn child were disposed of in a manner consistent with the disposal of

**R.S. 40:1299.35.14****MISCELLANEOUS HEALTH PROVISIONS****Note 1****Ch. 5**

other human remains, was an unconstitutional exercise of state's police power, because it required that fetal remains be treated with same dignity as remains of a person and, thereby, unduly burdened the right of a woman to obtain an abortion and represented an impermissible attempt of the state to influence woman's abortion decision. *Margaret S. v. Edwards*, D.C.1980, 488 F.Supp. 181.

performed, tell woman that she must choose between burial and other means of disposal of aborted fetus impermissibly intrudes into physician-patient relationship by requiring disclosure to be made even if physician knows it would be emotionally detrimental to his patient. *Margaret S. v. Treen*, D.C.1984, 597 F.Supp. 636, affirmed 794 F.2d 994.

**2. Physician-patient relationship**

Under R.S. 40:1299.35.14, requirement that physician, within 24 hours after abortion is

**§ 1299.35.15. Instructions to be provided subsequent to abortion**

Any physician who shall perform or induce an abortion, shall subsequent to the abortion being performed or induced, provide his patient with specific oral and written medical instructions to be followed by that patient in order to insure her safe recovery from the abortion.

Added by Acts 1978, No. 435, § 1.

**§§ 1299.35.16, 1299.35.17. Repealed by Acts 1981, No. 774, § 4, eff. July 23, 1981****Historical and Statutory Notes**

The repealed sections were added by Acts 1978, No. 435, § 1 and amended by Acts 1980, No. 418, § 1. Section 1299.35.16 related to standards for abortion facilities. Section 1299.35.17 related to licensing of abortion facilities and hospitals permitting abortions.

The provisions of the repealed sections, which required that all abortion facilities be

licensed by the Louisiana Department of Health and Human Resources and which set forth detailed standards for licensing, including drug and equipment requirements, were held unconstitutional in *Margaret S. v. Edwards*, D.C.1980, 488 F.Supp. 181.

**§ 1299.35.18. Penalties**

Whoever violates the provisions of this Part shall be fined not more than one thousand dollars, or imprisoned for not more than two years, or both.

Added by Acts 1978, No. 435, § 1. Amended by Acts 1981, No. 774, § 1, eff. July 23, 1981.

**Historical and Statutory Notes**

The 1981 amendment rewrote the section which previously read:

"A. Whoever violates R.S. 40:1299.35.2 through 40:1299.35.10 or R.S. 40:1299.35.13 through 40:1299.35.15 shall be fined not more than one thousand dollars and imprisoned for not more than two years or both.

"B. Whoever violates the licensing provisions of R.S. 40:1299.35.1 through

40:1299.35.18 shall be fined not more than one hundred dollars and imprisoned for not more than thirty days or both. Each day of operation of an abortion facility in violation of the licensing provisions of R.S. 40:1299.35.1 through 40:1299.35.18 shall constitute a separate offense."

**Law Review Commentaries**

Alternative means of reproduction: Virgin territory for legislation. Kathryn Venturatos Lorio, 44 La.L.Rev. 1641 (1984).

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**Note 1**

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**1. Validity**

Louisiana was empowered to place value upon prenatal human life, and such valuation, as manifested by its abortion statutes [this section and R.S. 37:1285(6) (see, now, R.S. 37:1285(8), (8.1), (9))] could not be struck down by federal court. *Rosen v. Louisiana State Bd. of Medical Examiners*, D.C.1970, 318 F.Supp. 1217, vacated 93 S.Ct. 2285, 412 U.S. 902, 36 L.Ed.2d 966.

The Louisiana abortion laws [this section and R.S. 37:1285(6) (see, now, R.S. 37:1285(8), (8.1), (9))] do not infringe any fundamental principle as understood by the traditions of our people. *Id.*

This section was not violative of the First, Fourth, Fifth, Ninth and Fourteenth Amendments (U.S.C.A. Const.Amend. 1, 4, 5, 9 and 14) and was not an unwarranted invasion of the private rights of a female person. *State v. Campbell*, 1972, 263 La. 1058, 270 So.2d 506.

This section, which was not arbitrary, unreasonable, or so vague as to be unconstitutional and which defined offense whose gravamen was intent with which artificial means are employed to procure expulsion of uterine contents, did not deny due process by failing to make actual delivery a necessary element of the crime. *State v. Scott*, 1971, 260 La. 190, 255 So.2d 736.

This section was not violative of defendant's rights under Ninth and Fourteenth Amendments of Federal Constitution (U.S. C.A. Const.Amend. 9, 14) on theory that it infringed upon right of women to choose whether they want to bear children, was overly broad, and impinged upon freedom to choose in the matter of abortions. *Id.*

This section outlawing abortion is constitutional. *State v. Shirley*, 1970, 256 La. 665, 237 So.2d 676, certiorari denied 91 S.Ct. 891, 401 U.S. 926, 27 L.Ed.2d 829, rehearing denied 91 S.Ct. 1383, 402 U.S. 925, 28 L.Ed.2d 664.

This statute is constitutional. *State v. Pesson*, 1970, 256 La. 201, 235 So.2d 568.

**2. In general**

State could not regulate first trimester abortions by requiring that all be performed in licensed hospital. *Emma G. v. Edwards*, D.C.1977, 434 F.Supp. 1048.

Louisiana Health and Human Resource Administration could not deny medicaid payments for therapeutic abortions performed outside hospital by qualified medical vendors. *Id.*

As used in this section, terms "embryo" and "fetus" refer to separate stages in pre-

natal development. *Rosen v. Louisiana State Bd. of Medical Examiners*, D.C.1970, 318 F.Supp. 1217, vacated 93 S.Ct. 2285, 412 U.S. 902, 36 L.Ed.2d 966.

In Louisiana, woman who procures abortion for herself is not criminally responsible. *Rosen v. Louisiana State Bd. of Medical Examiners*, D.C.1970, 318 F.Supp. 1217, vacated 93 S.Ct. 2285, 412 U.S. 902, 36 L.Ed.2d 966.

This section and R.S. 37:1285(6) (see, now, R.S. 37:1285(8), (8.1), (9)) prohibit performance of certain acts if made with intent to destroy embryo or fetus before natural birth, without regard to viability, unless the actor is a physician and the acts are performed for the relief of a woman whose life appears in peril. *Rosen v. Louisiana State Bd. of Medical Examiners*, D.C.1970, 318 F.Supp. 1217, vacated 93 S.Ct. 2285, 412 U.S. 902, 36 L.Ed.2d 966, conformed 380 F.Supp. 875, affirmed 95 S.Ct. 767, 419 U.S. 1098, 42 L.Ed.2d 795.

Actual delivery of embryo or fetus is not necessary element of offense of abortion. *State v. Pesson*, 1970, 256 La. 201, 235 So.2d 568.

A pregnant female who voluntarily becomes the subject of an abortion, without justifiable medical reason, is guilty of no criminal offense under this section. *Payne v. Louisiana Indus. Life Ins. Co.*, App.1948, 33 So.2d 444.

**3. Purpose**

Though Louisiana has demonstrated greater concern for life after birth than for life before birth, it is the policy of the Louisiana abortion statutes [this section and R.S. 37:1285(6) (see, now, R.S. 37:1285(8), (8.1), (9))] that whatever interests the pregnant woman or others may have in terminating pregnancy must be subordinated, except where the life of the woman is threatened, to afford the embryo or fetus the opportunity to develop toward natural birth. *Rosen v. Louisiana State Bd. of Medical Examiners*, D.C.1970, 318 F.Supp. 1217, vacated 93 S.Ct. 2285, 412 U.S. 902, 36 L.Ed.2d 966.

**4. Hospitals**

A public hospital should make its facilities available to staff physicians willing to perform elective nonmedically necessary abortions; however, no physician or supporting personnel who have religious or moral convictions against abortion are re-

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quired to participate in their performance. Op. Atty. Gen., No. 75-835, March 4, 1976.

#### 5. Indictment and information

Indictment charging defendant with "intent of procuring the premature delivery of the embryo and fetus" sufficiently informed accused of nature and cause of accusation notwithstanding terms embryo and fetus had different meanings. *State v. Scott*, 1971, 260 La. 190, 255 So.2d 736.

#### 6. Burden of proof

In prosecution for abortion, State has burden of proving intent. *State v. Campbell*, 1972, 263 La. 1058, 270 So.2d 506.

#### 7. Instructions

Charge to jury which contained R.S. 14:87 which defined crime of abortion was not improper on ground that it tended to sway the minds of the jury in favor of the State. *State v. Pesson*, 1970, 256 La. 201, 235 So.2d 568.

#### 8. Review

Defendant in abortion prosecution would not be heard for first time on appeal to complain that reading R.S. 14:87 defining crime of abortion to jury was improper on ground statute was unconstitutional and that the charge was drafted so as to sway minds of jury in favor of the State. *State v. Pesson*, 1970, 256 La. 201, 235 So.2d 568.

### § 87.1. Killing a child during delivery

Killing a child during delivery is the intentional destruction, during parturition of the mother, of the vitality or life of a child in a state of being born and before actual birth, which child would otherwise have been born alive; provided, however, that the crime of killing a child during delivery shall not be construed to include any case in which the death of a child results from the use by a physician of a procedure during delivery which is necessary to save the life of the child or of the mother and is used for the express purpose of and with the specific intent of saving the life of the child or of the mother.

Whoever commits the crime of killing a child during delivery shall be imprisoned at hard labor in the penitentiary for life.

Added by Acts 1973, No. 74, § 1.

#### Cross References

Nutritional or medical deprivation of infants, see R.S. 40:1299.36.1 et seq.

#### Law Review Commentaries

Work of the Louisiana appellate courts for 1974-1975 term: Criminal law. Dale E. Bennett, 36 La.L.Rev. 502 (1976).

#### Library References

Abortion and Birth Control ¶1, 15.  
C.J.S. Abortion and Birth Control; Family Planning §§ 2 to 9, 12.

### § 87.2. Human experimentation

Human experimentation is the use of any live born human being, without consent of that live born human being, as hereinafter defined, for any scientific or laboratory research or any other kind of experimentation or study except to protect or preserve the life and health of said live born human being, or the conduct, on a human embryo or fetus in utero, of any experimentation or study except to preserve the life or to improve the health of said human embryo or fetus.

A human being is live born, or there is a live birth, whenever there is the complete expulsion or extraction from its mother of a human embryo or fetus, irrespective of the duration of pregnancy, which after such separation, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.

Whoever commits the crime of human experimentation shall be imprisoned at hard labor for not less than five nor more than twenty years, or fined not more than ten thousand dollars, or both.

Added by Acts 1973, No. 77, § 1.

#### Cross References

Experimentation on unborn child or child born as result of abortion, see R.S. 40:1299.35.13.

#### Law Review Commentaries

Alternative means of reproduction: Virgin territory for legislation. Kathryn Venturatos Lorio, 44 La.L.Rev. 1641 (1984).

#### Library References

Physicians and Surgeons ⇨8, 15.  
C.J.S. Physicians and Surgeons §§ 5, 40, 48.

### § 87.3. [Blank]

### § 87.4. Abortion advertising

Abortion advertising is the placing or carrying of any advertisement of abortion services by the publicizing of the availability of abortion services.

Whoever commits the crime of abortion advertising shall be imprisoned, with or without hard labor, for not more than one year or fined not more than five thousand dollars, or both.

Added by Acts 1973, No. 76, § 1.

#### Library References

Abortion and Birth Control ⇨1, 15.  
C.J.S. Abortion and Birth Control; Family Planning §§ 2 to 9, 12.

### § 87.5. Intentional failure to sustain life and health of aborted viable infant

The intentional failure to sustain the life and health of an aborted viable infant shall be a crime. The intentional failure to sustain the life and health of an aborted viable infant is the intentional failure, by any physician or person performing or inducing an abortion, to exercise that degree of professional care and diligence, and to perform such measures



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as constitute good medical practice, necessary to sustain the life and health of an aborted viable infant, when the death of the infant results. For purposes of this Section, "viable" means that stage of fetal development when the life of the unborn child may be continued indefinitely outside the womb by natural or artificial life-supporting systems. Any person who commits the crime of intentional failure to sustain the life and health of an aborted viable infant shall be imprisoned at hard labor for not more than twenty-one years.

Added by Acts 1977, No. 406, § 1.

#### Cross References

Failure to sustain life and health of aborted viable infant, effect on license to practice medicine, surgery, osteopathy or midwifery, see R.S. 37:1285.  
Nutritional or medical deprivation of infants, see R.S. 40:1299.36.1 et seq.

#### Library References

Abortion and Birth Control 8-1, 15. Words and Phrases (Perm.Ed.)  
C.J.S. Abortion and Birth Control; Family  
Planning §§ 2 to 9, 12.

### § 88. Distribution of abortifacients

Distribution of abortifacients is the intentional:

- (1) Distribution or advertisement for distribution of any drug, potion, instrument, or article for the purpose of procuring an abortion; or
- (2) Publication of any advertisement or account of any secret drug or nostrum purporting to be exclusively for the use of females, for preventing conception or producing abortion or miscarriage.

Whoever commits the crime of distribution of abortifacients shall be fined not more than five hundred dollars, or imprisoned for not more than six months, or both.

#### Reporter's Comment

##### Louisiana statutes covered:

Acts 1920, No. 88, §§ 1, 2 (selling or advertising of drugs or instruments for procuring abortion).

Acts 1920, No. 95, § 1 (advertising drugs preventing conception or causing abortion).

##### In general:

Upon the express instructions of the Council of the Institute, the two statutes

cited above were combined and retained, the only modification amounting to a purely formal one, to make the form of the section consistent with the rest of the Code.

#### History and Source of Law

##### Source:

Acts 1942, No. 43, § 1, Art. 88.

#### Law Review Commentaries

Abortion: A proposal for reform. 43 Tulane L.Rev. 834 (1969).

Analysis of the Criminal Code. Clarence J. Morrow, 17 Tulane L.Rev. 1, 21 (1942).

**§ 87.2. Human experimentation**

**Historical and Statutory Notes**

**1989 Legislation**

**Legislative intent.** See House Concurrent Resolution No. 10 of the 1989 Second Extraordinary Session, preceding R.S. 14:87.

**United States Supreme Court**

Due process, viability testing of fetuses, state's interest in protecting potential human life, see *Webster v. Reproductive Health Services*, 1989, 109 S.Ct. 3040, 106 L.Ed.2d 410.

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**§ 1592. Discrimination for refusal**

No person, hospital, health care facility, firm, association, corporation or educational institution, directly or indirectly, by himself or another, shall discriminate against any physician, nurse or other person by refusing or withholding employment from or denying admittance, when such physician, nurse or other person refuses to perform, or assist in the performance of an abortion, nor shall such refusal constitute grounds for loss of any privileges or immunities to which such physician, nurse or other person would otherwise be entitled.

1977, c. 696, § 186, eff. March 31, 1978.

**Historical and Statutory Notes**

**Derivation:**

Laws 1973, c. 518, § 2.

Laws 1977, c. 696, § 183.

Former § 1573 of this title.

**Library References**

**American Digest System**

Abortion and birth control; civil liability, see  
Abortion and Birth Control ¶16.

**Encyclopedias**

Regulation of abortion in general, see C.J.S.  
Abortion and Birth Control; Family Plan-  
ning § 7.

**WESTLAW Research**

Abortion and birth control cases: 4k[add key  
number].

**§ 1593. Sale and use of fetuses**

Whoever shall use, transfer, distribute or give away any live human fetus, whether intrauterine or extrauterine, or any product of conception considered live born for scientific experimentation or for any form of experimentation shall be punished by a fine of not more than \$5,000 and by imprisonment for not more than 5 years and any person consenting, aiding or assisting shall be liable to like punishment.

1977, c. 696, § 186, eff. March 31, 1978.

**Historical and Statutory Notes**

**Derivation:**

Laws 1973, c. 518, § 3.

Laws 1977, c. 696, § 183.

Former § 1574 of this title.

**Library References**

**American Digest System**

Abortion and birth control; sentence and pun-  
ishment, see Abortion and Birth Control  
¶15.

**Encyclopedias**

Right to, and regulation of abortion; trial, sentence, and punishment, see C.J.S. Abor-

tion and Birth Control; Family Planning § 12.

**WESTLAW Research**

Abortion and birth control cases: 4k[add key number].

**§ 1594. Failure to preserve life of live born person**

Whenever an abortion procedure results in a live birth, failure to take all reasonable steps, in keeping with good medical practice, to preserve the life and health of the live born person shall subject the responsible party or parties to Maine law governing homicide, manslaughter and civil liability for wrongful death and medical malpractice.

1977, c. 696, § 186, eff. March 31, 1978.

**Historical and Statutory Notes****Derivation:**

Laws 1973, c. 518, § 4.

Laws 1977, c. 696, § 183.

Former § 1575 of this title.

**Cross References**

Health Security Act, see § 2501 et seq. of title 24.

Homicide, generally, see § 201 et seq. of title 17-A.

Manslaughter, see § 203 of title 17-A.

Wrongful death, see § 2-804 of title 18-A.

**Library References****American Digest System**

Right to abortion and regulation thereof, see  
Abortion and Birth Control ¶50.

**Encyclopedias**

Regulation of abortion in general, see C.J.S.  
Abortion and Birth Control; Family Plan-  
ning § 4.

**WESTLAW Research**

Abortion and birth control cases: 4k[add key number].

**§ 1595. Live born and live birth, defined**

"Live born" and "live birth," as used in this chapter, shall mean a product of conception after complete expulsion or extraction from its mother; irrespective of the duration of pregnancy, which breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the

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placenta is attached. Each product of such a birth is considered live born and fully recognized as a human person under Maine law.  
1977, c. 696, § 186, eff. March 31, 1978.

**Historical and Statutory Notes**

<b>Derivation:</b>	Laws 1977, c. 696, § 183.
Laws 1973, c. 518, § 5.	Former § 1576 of this title.

**Library References**

**American Digest System**

Right to abortion and regulation thereof, see  
Abortion and Birth Control ¶.50.

**Encyclopedias**

Regulation of abortion in general, see C.J.S.  
Abortion and Birth Control; Family Plan-  
ning § 4.

**WESTLAW Research**

Abortion and birth control cases: 4k[add key  
number].

**§ 1596. Abortion and miscarriage data**

**1. Definitions.** As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Abortion" means the intentional interruption of a pregnancy by the application of external agents, whether chemical or physical, or the ingestion of chemical agents with an intention other than to produce a live birth or to remove a dead fetus, regardless of the length of gestation.

B. "Miscarriage" means an interruption of a pregnancy other than as provided in paragraph A of a fetus of less than 20 weeks gestation.

**2. Abortion reports.** A report of each abortion performed shall be made to the Department of Human Services on forms prescribed by the department. These report forms shall not identify the patient by name or otherwise and shall contain only the information requested on the United States Standard Report of Induced Termination of Pregnancy, published by the National Center for Health Statistics, dated January 1978, or any more recent revision of a standard report form.

The form containing that information and data shall be prepared and signed by the attending physician and transmitted to the department not later than 10 days following the end of the month in which the abortion is performed.

A physician who reports data on an abortion pursuant to this section shall be immune from any criminal liability for that abortion under section 1598.

**3. Miscarriage reports.** A report of each miscarriage shall be made by the physician in attendance at or after the occurrence of the miscarriage to the

**§ 12J. Experimentation on human fetuses prohibited; medical procedures authorized; consent; approval; civil and criminal liability and proceedings; severability**

(a) I. No person shall use any live human fetus whether before or after expulsion from its mother's womb, for scientific, laboratory, research or other kind of experimentation. This section shall not prohibit procedures incident to the study of a human fetus while it is in its mother's womb, provided that in the best medical judgment of the physician, made at the time of the study, said procedures do not substantially jeopardize the life or health of the fetus, and provided said fetus is not the subject of a planned abortion. In any criminal proceeding a fetus shall be conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the study, that she was not planning an abortion.

This section shall not prohibit or regulate diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus involved or to preserve the life or health of the fetus involved or the mother involved.

A fetus is a live fetus for purposes of this section when, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development.

(a) II. No experimentation may knowingly be performed upon a dead fetus unless the consent of the mother has first been obtained, provided, however, that such consent shall not be required in the case of a routine pathological study. In any criminal proceeding, consent shall be conclusively presumed to have been granted for the purposes of this section by a written statement, signed by the mother who is at least eighteen years of age, to the effect that she consents to the use of her fetus for scientific, laboratory, research or other kind of experimentation or study;

such written consent shall constitute lawful authorization for the transfer of the dead fetus.

(a) III. No person shall perform or offer to perform an abortion where part or all of the consideration for said performance is that the fetal remains may be used for experimentation or other kind of research or study.

(a) IV. No person shall knowingly sell, transfer, distribute or give away any fetus for a use which is in violation of the provisions of this section. For purposes of this section, the word "fetus" shall include also an embryo or neonate.

(a) V. Except as hereafter provided, whoever violates the provisions of this section shall be punished by imprisonment in a jail or house of correction for not less than one year nor more than two and one-half years or by imprisonment in the state prison for not more than five years and by the imposition of a fine of up to ten thousand dollars.

(a) VI. In any criminal action under this subsection (a), it shall be a complete defense that at the time of its performance the subject procedure had received the written approval of a duly appointed Institutional Review Board provided that such Board sets forth in its written approval that the procedure does not violate the provisions of this subsection (a) and sets forth therein a reasonable basis for such conclusion and provided that there was not outstanding, at any time that the subject procedure was being performed, a judgment of a court entered pursuant to the provisions of subsection (b), that the subject procedure violates the provisions of this subsection (a). The written approval shall contain a detailed description of the procedure by attachment of a protocol or other writing or otherwise and shall be maintained as a permanent record by such Board or by the hospital or other institution for which the Board acts.

A copy of the written approval, together with any attached protocol or other writing, shall be filed with the office of the District Attorney for the county in which the hospital or other institution for which the board acts, is located. Such copy shall be available for public inspection at reasonable times. No member of an Institutional Review Board voting not to approve a procedure, or not present at such a vote, shall be criminally or civilly liable for such approval by the Institutional Review Board or for the performance of the procedure by others. No member of such a Board voting to approve a procedure shall be criminally or civilly liable for such approval by him or the performance of the procedure by others if, based on the written approval and the basis thereof referred to above, such a member acts on a good faith belief that the procedure does not violate the provisions of this section.

(a) VII. Where there is outstanding such a judgment that the subject procedure violates the provisions of this subsection (a), it shall not constitute a defense that the person performing said procedure did not

receive notice, or otherwise know, of that judgment; provided, however, that until the District Attorney files a copy of the judgment prohibiting a procedure with the Commissioner of Public Health as provided in subsection (b) VII it shall constitute a defense that the person performing the subject procedure did not have notice of the judgment and that he had obtained the approval of the Institutional Review Board for the subject procedure as provided in subsection (a) VI.

(b) I. Whenever a procedure has been approved by a duly appointed Institutional Review Board which the District Attorney for the district where said procedure is performed has reasonable grounds to believe is prohibited under the provisions of subsection (a), he shall file a complaint in the Superior Court sitting in a county where the procedure is performed seeking a determination of whether said procedure violates the provisions of this statute. The complaint shall describe the procedure and the reason or reasons why there are reasonable grounds to believe that the said procedure is in violation of the provisions of this statute. The complaint shall name as defendants those persons within his jurisdiction whom the District Attorney reasonably believes have performed, are performing, or are about to perform, the described procedure and those institutions within his jurisdiction in which said procedure has been performed, is being performed, or is about to be performed; such defendants shall be served with a copy of the complaint and a summons in accordance with the provisions of Rule 4 of the Massachusetts Rules of Civil Procedure. Upon the filing of the complaint, notice thereof shall be given by the District Attorney, by certified or registered mail, to the Commissioner of Public Health, who in turn shall give the same notice to those institutions in the Commonwealth who, in the judgment of said Commissioner, may be affected by a judgment in the action, and in any event to all of the licensed medical schools in the Commonwealth.

(b) II. Any person or institution which has performed, is performing, or is about to perform, a procedure, may file a complaint in the Superior Court seeking a determination of whether said procedure violates the provision of this statute. Said determination may be sought irrespective of whether said procedure has been approved by an institutional review board. The complaint, which shall have attached thereto a copy of any protocol relative to said procedure, shall describe the procedure and state the reason or reasons which cause the plaintiff to seek the judicial determination. The complaint shall name the District Attorney for the district where the procedure is performed as defendant in the action and he shall be served with a copy of the complaint, including the attached protocol, if any, and the summons in accordance with the provisions of Rule 4 of the Massachusetts Rules of Civil Procedure. Service shall be made by delivery to the office of said District Attorney; or by mailing by certified or registered mail to said office. Upon receipt of service, notice shall be given by the District Attorney, by certified or registered mail, to the Commissioner of Public Health who in turn shall give notice to those institutions who in the judgment of said commissioner may be affected



by a judgment in the action, and in any event to all of the licensed medical schools in the Commonwealth.

(b) III. Any person or institution desiring to intervene in the action may file a motion to intervene with the court in which the action is pending within ten days from the mailing of such notice, except that the court, for good cause shown, may allow said motion after the ten-day period. A copy of the motion to intervene shall also be served upon the District Attorney and upon the persons or institutions initiating the action or against whom the action has been initiated. The motion shall be signed and certified under oath by the applicant and shall state the grounds therefore showing that the applicant claims an interest in the issue of the lawfulness of the subject procedure in that he has performed said procedure, or that he is performing said procedure, or that he is about to perform said procedure, and that the disposition of the action may impair or impede his ability to perform or continue to perform said procedure. Upon a determination by the court that the applicant has satisfied the requirement of this section, the court shall allow the applicant to intervene in the action.

(b) IV. After service of the complaint upon an original party, such party shall serve and file an answer within twenty days unless otherwise directed by order of the court. The answer shall state whether, in the opinion of the pleader, the subject procedure is prohibited by the provisions of this statute and the reason or reasons for such opinion. An intervenor may serve and file a pleading in support of either the complaint or answer within ten days from receipt of notice of the granting of the motion to intervene. Unless the court otherwise orders, no response to the pleading of an intervenor is required.

(b) V. Any party may move for summary judgment, in accordance with Rule 56 of the Massachusetts Rules of Civil Procedure, or for judgment on the pleadings in accordance with Rule 12(c) of the Massachusetts Rules of Civil Procedure. If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion.

(b) VI. Any trial on the merits shall be without a jury. The court shall find the facts specially and shall set forth in writing separately its findings of facts and conclusions of law thereon and shall enter judgment accordingly. Such judgment may be appealed to the Supreme Judicial Court. Until reversed, however, by the Supreme Judicial Court, such judgment shall constitute an in rem judgment, binding within the Commonwealth of Massachusetts, that the subject procedure is prohibited or is not prohibited by the provisions of this statute.

(b) VII. Upon the entry of a judgment that a procedure is prohibited by the provisions of this statute, the District Attorney shall promptly give notice by publication in a newspaper of general circulation in each of

the counties of the Commonwealth and by sending notification by registered or certified mail to each licensed hospital and medical school in the Commonwealth; such notice shall contain a description of the prohibited medical procedure and shall state that the performance of such procedure constitutes a crime punishable under the provisions of this statute. A copy of all judgments and accompanying opinions permitting or prohibiting a procedure shall be filed by the District Attorney with the Commissioner of Public Health. The Commissioner of Public Health shall maintain a permanent file of such judgments and opinions for public inspection.

(b) VIII. Any action brought under this statute to determine whether a procedure is prohibited by the provisions of this statute and any appeal of a judgment that a procedure is or is not prohibited by the provisions of this statute shall be advanced for a prompt and speedy disposition consistent, however, with a reasonable opportunity being afforded to the parties to properly prepare the case.

(b) IX. If any section, subsection, paragraph, sentence or clause of this statute is held to be unconstitutional, such holding shall not affect the remaining portions of this statute.

Added by St.1974, c. 421. Amended by St.1976, c. 551.

#### Historical Note

St.1974, c. 421, was approved June 26, 1974, introductory exception clause, and added "and by the imposition of a fine of up to ten

St.1976, c. 551, approved Oct. 27, 1976, in the provisions of subsec. (a) V, inserted the thousand dollars"; and added the provisions of subsec. (a) VI to (b) IX.

#### Library References

Comments.

Abortion, see M.P.S. vol. 17A, Bishop, § 1367.

Fetal experimentation, see M.P.S. vol. 17A, Bishop, § 1627.5.

**ADMINISTRATION**

**333.2685**

**Historical and Statutory Notes**

**Source:**

P.A.1978, No. 368, § 2678, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2678.

**Prior Laws:**

P.A.1947, No. 241, § 4.  
C.L.1948, § 325.404.  
C.L.1970, § 325.404.

**Cross References**

Confidentiality, data and records, see § 333.2631.  
Disclosure, data and records, see § 333.2632.  
Savings clauses and effective dates, see § 333.25201 et seq.  
Unlawful disclosure, penalty, see § 333.2638.  
Vital records, application of part, see §§ 333.2876, 333.2881.

**Michigan Administrative Code**

For Rules and Regulations, see Rules 325.921 et seq., 325.951 et seq., Michigan Administrative Code.

**Library References**

M.L.P. Death; Dead Bodies §§ 71, 73.  
M.L.P. Health § 5.

**333.2685. Human research; use of human embryo, fetus or neonate**

Sec. 2685. (1) A person shall not use a live human embryo, fetus, or neonate for nontherapeutic research if, in the best judgment of the person conducting the research, based upon the available knowledge or information at the approximate time of the research, the research substantially jeopardizes the life or health of the embryo, fetus, or neonate. Nontherapeutic research shall not in any case be performed on an embryo or fetus known by the person conducting the research to be the subject of a planned abortion being performed for any purpose other than to protect the life of the mother.

(2) For purposes of subsection (1) the embryo or fetus shall be conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the research, that she was not planning an abortion.

**Historical and Statutory Notes**

**Source:**

P.A.1978, No. 368, § 2685, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2685.

**Law Review Commentaries**

*In Vitro* fertilization and cryopreservation. Juridical status of fetus: Proposal for legal protection of unborn. Patricia A. King, 77 Mich.L.Rev. 1647 (1979).  
Gail D. Sillman, 67 Mich.B.J. 601 (1988).

**Library References**

M.L.P. Abortion § 1.  
M.L.P. Health § 1.

## **333.2686**

## **HEALTH**

### **333.2686. Procedures not prohibited; embryo, fetus or neonate**

Sec. 2686. Sections 2685 to 2691<sup>1</sup> shall not prohibit or regulate diagnostic, assessment, or treatment procedures, the purpose of which is to determine the life or status or improve the health of the embryo, fetus, or neonate involved or the mother involved.

<sup>1</sup> Sections 333.2685 to 333.2691.

#### **Historical and Statutory Notes**

##### **Source:**

P.A.1978, No. 368, § 2686, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2686.

### **333.2687. Live embryo, fetus or neonate; determination**

Sec. 2687. An embryo, fetus, or neonate is a live embryo, fetus, or neonate for purposes of sections 2685 to 2691<sup>1</sup> if, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted embryo or fetus at approximately the same stage of gestational development.

<sup>1</sup> Sections 333.2685 to 333.2691.

#### **Historical and Statutory Notes**

##### **Source:**

P.A.1978, No. 368, § 2687, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2687.

### **333.2688. Research upon dead embryo, fetus or neonate; consent**

Sec. 2688. (1) Research may not knowingly be performed upon a dead embryo, fetus, or neonate unless the consent of the mother has first been obtained. Consent shall not be required in the case of a routine pathological study.

(2) For purposes of this section, consent shall be conclusively presumed to have been granted by a written statement, signed by the mother that she consents to the use of her dead embryo, fetus, or neonate for research.

(3) Written consent shall constitute lawful authorization for the transfer of the dead embryo, fetus, or neonate to medical research facilities.

(4) Research being performed upon a dead embryo, fetus, or neonate shall be conducted in accordance with the same standards applicable to research conducted pursuant to part 101.<sup>1</sup>

<sup>1</sup> Section 333.10101 et seq.

#### **Historical and Statutory Notes**

##### **Source:**

P.A.1978, No. 368, § 2688, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2688.

## ADMINISTRATION

**333.2691**

### Cross References

Abortion, reports, see § 333.2835.  
Anatomical gifts, see § 333.10101 et seq.  
Fetal death, reports, see § 333.2834.  
Freedom of Information Act, see § 15.231 et seq.

### **333.2689. Abortion; research or study upon fetus or embryo as a consideration of performance**

Sec. 2689. A person shall not perform or offer to perform an abortion where part or all of the consideration for the performance is that the embryo, or fetus, whether alive or dead, may be used for research or study.

### Historical and Statutory Notes

#### Source:

P.A.1978, No. 368, § 2689, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2689.

### Library References

M.L.P. Abortion § 1.  
M.L.P. Health § 1.

### **333.2690. Sale, transfer, distribution or giving away fetus, embryo or neonate in violation of code**

Sec. 2690. A person shall not knowingly sell, transfer, distribute, or give away an embryo, fetus, or neonate for a use which is in violation of sections 2685 to 2689.<sup>1</sup>

<sup>1</sup> Sections 333.2685 to 333.2689.

### Historical and Statutory Notes

#### Source:

P.A.1978, No. 368, § 2690, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2690.

### **333.2691. Violations; penalty**

Sec. 2691. A person who violates sections 2685 to 2690<sup>1</sup> is guilty of a felony, punishable by imprisonment for not more than 5 years.

<sup>1</sup> Sections 333.2685 to 333.2690.

### Historical and Statutory Notes

#### Source:

P.A.1978, No. 368, § 2691, Eff. Sept. 30, 1978.  
C.L.1970, § 333.2691.

### Library References

Health and Environment ⇌37.  
WESTLAW Topic No. 199.  
C.J.S. Health and Environment §§ 48, 113,  
114, 141, 143, 148, 149, 155.

M.L.P. Abortion § 1.  
M.L.P. Health § 1.

**333.2692. Nontherapeutic research, definition**

Sec. 2692. As used in sections 2685 to 2691,<sup>1</sup> “nontherapeutic research” means scientific or laboratory research, or other kind of experimentation or investigation not designed to improve the health of the research subject.

<sup>1</sup> Sections 333.2685 to 333.2691.

**Historical and Statutory Notes****Source:**

P.A.1978, No. 368, § 2692, Eff. Sept. 30, 1978.

C.L.1970, § 333.2692.

*Part 27. Michigan Essential Health Provider Recruitment Strategy Act**Caption editorially supplied**Analysis of Sections***Section**

- 333.2701. Definitions.
- 333.2703. Essential health provider recruitment strategy.
- 333.2705. Health provider debt repayment program; service obligation.
- 333.2707. Minority student grant program; service obligation.
- 333.2709. Nurse midwifery service.
- 333.2711. Designated physician specialty areas; recruitment preference.
- 333.2713. Service obligations; determination, placement community.
- 333.2715. Eligibility for funds.
- 333.2717. Health resource shortage area; identification and designation, criteria.
- 333.2719. Guidelines for assignments.
- 333.2721. Minority health profession grant fund.
- 333.2723. Rules; report to legislature.
- 333.2725. Short title.
- 333.2727. Effective date.

**333.2701. Definitions**

Sec. 2701. As used in this part:

(a) “Board certified” means certified to practice in a particular medical specialty by a national board recognized by the American board of medical specialties or the American osteopathic association.

(b) “Certified nurse midwife” means an individual licensed as a registered professional nurse under part 172<sup>1</sup> who has been issued a specialty certification in the practice of nurse midwifery by the board of nursing under section 17210.<sup>2</sup>

(c) “Certified nurse practitioner” means an individual licensed as a registered professional nurse under part 172 who has been issued a specialty certification as a nurse practitioner by the board of nursing under section 17210.

(d) “Designated nurse” means a certified nurse midwife or certified nurse practitioner.

(e) “Designated physician” means a physician qualified in 1 of the physician specialty areas identified in section 2711.<sup>3</sup>

(f) “Designated professional” means a designated physician, designated nurse, or physician’s assistant.

(g) "Health resource shortage area" means a geographic area, population group, or health facility designated by the department under section 2717.<sup>4</sup>

(h) "Medicaid" means benefits under the program of medical assistance established under title XIX of the social security act, 42 U.S.C. 1396 to 1396d, 1396f to 1396g, and 1396i to 1396s, and administered by the department of social services under the social welfare act, Act No. 280 of the Public Acts of 1939, being sections 400.1 to 400.121 of the Michigan Compiled Laws.

(i) "Medical school" means an accredited program for the training of individuals to become physicians.

(j) "Medicare" means benefits under the federal medicare program established under title XVIII of the social security act, 42 U.S.C. 1395 to 1395b, 1395b-2 to 1395i, 1395i-1a to 1395i-2, 1395j to 1395dd, 1395ff to 1395mm, and 1395oo to 1395ccc.

(k) "National health service corps" means the agency established under section 331 of title III of the public health service act, 42 U.S.C. 254d.

(l) "Nurse" means an individual licensed to engage in the practice of nursing under part 172.

(m) "Nursing program" means an accredited program for the training of individuals to become nurses.

(n) "Physician" means an individual licensed as a physician under part 170<sup>5</sup> or an osteopathic physician under part 175.<sup>6</sup>

(o) "Physician's assistant" means an individual licensed as a physician's assistant under part 170 or part 175.<sup>7</sup>

(p) "Physician's assistant program" means an accredited program for the training of individuals to become physician's assistants.

(q) "Service obligation" means the contractual obligation undertaken by an individual under section 2705 or section 2707<sup>8</sup> to provide health care services for a determinable time period at a site designated by the department. P.A.1978, No. 368, § 2701, added by P.A.1990, No. 16, § 1, Eff. Oct. 1, 1990.

<sup>1</sup> Section 333.17201 et seq.

<sup>2</sup> Section 333.17210.

<sup>3</sup> Section 333.2711.

<sup>4</sup> Section 333.2717.

<sup>5</sup> Section 333.17001 et seq.

<sup>6</sup> Section 333.17501 et seq.

<sup>7</sup> Section 333.17001 et seq. or 333.17501 et seq.

<sup>8</sup> Section 333.2705 or 333.2707.

#### Historical and Statutory Notes

For effective date provisions of P.A.1990, No. 16, see § 333.2727 and the Historical and Statutory Notes following.

#### WESTLAW Electronic Research

See WESTLAW Electronic Research Guide following the Preface.

**Minn. Stat. Ann. §§ 145.421-145.422 (West 1989)**

**§ 145.416**

**PUBLIC HEALTH**

**Note 1**

to extent that such regulations applied to any abortion to be performed in first trimester of pregnancy. *Hodgson v. Anderson*, D.C.1974, 378 F.Supp. 1008, appeal dismissed 95 S.Ct. 819, 420 U.S. 903, 42 L.Ed.2d 833, affirmed in part, reversed in part 542 F.2d 1350.

**145.42. Abortions; nonliability for refusal to perform**

Subdivision 1. No physician, nurse, or other person who refuses to perform or assist in the performance of an abortion, and no hospital that refuses to permit the performance of an abortion upon its premises, shall be liable to any person for damages allegedly arising from the refusal.

Subd. 2. No physician, nurse, or other person who refuses to perform or assist in the performance of an abortion shall, because of that refusal, be dismissed, suspended, demoted, or otherwise prejudiced or damaged by a hospital with which the person is affiliated or by which the person is employed.

Laws 1971, c. 693, §§ 1, 2, eff. June 4, 1971. Amended by Laws 1986, c. 444.

**Historical Note**

Laws 1986, c. 444, authorized the removal of nonsubstantive gender specific references.

**Cross References**

Refusal to perform abortion, see § 145.414.

**Library References**

Hospitals ⇐7.	C.J.S. Physicians, Surgeons, and Other
Physicians and Surgeons ⇐15(6).	Health-Care Providers §§ 70, 75, 97 to 100.
C.J.S. Hospitals § 8.	

**United States Supreme Court**

Hospitalization for abortion. Planned Parenthood Association of Kansas City, M. v. Ash-	croft, 1983, 103 S.Ct. 2517, 462 U.S. 476, 76 L.Ed.2d 733.
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**145.421. Human conceptus, experimentation, research or sale; definitions**

**Subdivision 1. Terms.** As used in this section and section 145.422, the terms defined in this section shall have the meanings given them.

**Subd. 2. Human conceptus.** "Human conceptus" means any human organism, conceived either in the human body or produced in an artificial environment other than the human body, from fertilization through the first 265 days thereafter.

**Subd. 3. Living.** "Living", as defined for the sole purpose of this section and section 145.422, means the presence of evidence of life, such as movement, heart or respiratory activity, the presence of electroencephalographic or electrocardiographic activity.

Laws 1973, c. 562, § 1, eff. May 24, 1973.

**Cross References**

Live children, abortion, medical aid, see § 145.423.



## **PUBLIC HEALTH**

## **§ 145.423**

### **145.422. Experimentation or sale**

Subdivision 1. Whoever uses or permits the use of a living human conceptus for any type of scientific, laboratory research or other experimentation except to protect the life or health of the conceptus, or except as herein provided, shall be guilty of a gross misdemeanor.

Subd. 2. The use of a living human conceptus for research or experimentation which verifiable scientific evidence has shown to be harmless to the conceptus shall be permitted.

Subd. 3. Whoever buys or sells a living human conceptus or nonrenewable organ of the body is guilty of a gross misdemeanor. Nothing in this subdivision prohibits (1) the buying and selling of a cell culture line or lines taken from a nonliving human conceptus; (2) payments for reasonable expenses associated with the removal, storage, and transportation of a human organ, including payments made to or on behalf of a living organ donor for actual expenses such as medical costs, lost income, or travel expenses that are incurred as a direct result of the donation of the nonrenewable organ; or (3) financial assistance payments provided under insurance and medicare reimbursement programs.

Laws 1973, c. 562, § 2, eff. May 24, 1973. Amended by Laws 1984, c. 475, § 1.

#### **Historical Note**

The 1984 amendment rewrote subd. 3, which formerly read:

"If a child described in subdivision 1 dies after birth, the body shall be disposed of in accordance with the provisions of Minnesota Statutes, Sections 145.14 to 145.163."

Laws 1984, c. 475, § 2, provided that this amendment applied to crimes occurring on or after August 1, 1984.

### **145.423. Abortion; live births**

Subdivision 1. A live child born as a result of an abortion shall be fully recognized as a human person, and accorded immediate protection under the law. All reasonable measures consistent with good medical practice, including the compilation of appropriate medical records, shall be taken to preserve the life and health of the child.

Subd. 2. When an abortion is performed after the twentieth week of pregnancy, a physician, other than the physician performing the abortion, shall be immediately accessible to take all reasonable measures consistent with good medical practice, including the compilation of appropriate medical records, to preserve the life and health of any live birth that is the result of the abortion.

Subd. 3. If a child described in subdivision 1 dies after birth, the body shall be disposed of in accordance with the provisions of sections 145.14 to 145.163.

Laws 1976, c. 170, § 1.

145.1621. Disposition of aborted or miscarried fetuses

Notes of Decisions

Construction and application 2  
Validity 1

1. Validity

Legislature's use of term "dignified" in preamble of fetal disposal requirement in this section did not render requirement unconstitutionally vague, inasmuch as any ambiguity created by preamble was obviated by common terms used later in this section. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

Minnesota's fetal disposition requirement in this section did not burden abortion choice, despite clinic's contentions that law resulted in increased cost and psychological trauma to women seeking abortions. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

That application of Minnesota's fetal disposition requirement in this section was triggered only when remains of human fetus obtained through abortion or miscarriage had reached "stage of development so that there are cartilaginous structures, fetal or skeletal parts" did not render requirement unconstitutionally vague, inasmuch as application of this section could be validly determined in many instances, even though there would be cases in which need for compliance would be difficult to determine. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

That district court could not determine whether group disposal of fetal remains was "dignified" within meaning of preamble to Minnesota's fetal

disposition requirement in this section did not render requirement unconstitutionally vague; whether or not group disposal was authorized, district court could have upheld requirement based on valid application in case of individual cremation or interment. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

That Minnesota's fetal disposition requirement in this section did not apply to abortions or miscarriages occurring outside hospitals or clinics did not render requirement unconstitutionally underinclusive. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

That Minnesota's fetal disposition requirement in this section applied to both voluntary abortions and spontaneous miscarriages did not render requirement unconstitutionally overinclusive. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

2. Construction and application

Minnesota's fetal disposition requirement in this section allows group disposal of fetal remains. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

Administrative rule requiring cremation to be accomplished 72 hours from time of death and prohibiting commingling of ashes without written permission from next of kin did not apply to Minnesota's fetal disposition requirement in this section, which allowed group disposal of fetal remains. *Planned Parenthood of Minnesota v. State of Minn.*, C.A. 8 (Minn.)1990, 910 F.2d 479.

145.34, 145.35. Repealed by Laws 1991, c. 202, § 42

145.38 to 145.40. Repealed by Laws 1992, c. 485, § 3

Historical and Statutory Notes

The repealed sections limited the sale, display, and use of certain kinds of glue or cement.

Laws 1992, c. 485, § 4, provides in part that the repeal of these sections are effective July 1, 1992,

and apply to crimes committed on or after that date.

See, now, § 609.684.

145.406. Information on the sale and use of toxic substances

The commissioner of health shall prepare and distribute materials designed to provide information to retail businesses on the requirements of section 609.684.

Laws 1989, c. 282, art. 2, § 31. Amended by Laws 1992, c. 485, § 1.

Historical and Statutory Notes

1992 Legislation

The 1992 amendment corrected citations.

**145.411. Regulation of abortions; definitions****United States Supreme Court**

Unmarried natural father's right to prevent abortion, see *Doe v. Smith*, 1988, 108 S.Ct. 2136, 486 U.S. 1308, 100 L.Ed.2d 909.

**145.412. Criminal acts****United States Supreme Court**

Due process,

Abortion before viability, undue burden test, medical emergency, informed consent, waiting period, parental consent, reporting and recordkeeping, spousal notification, see *Planned Parenthood v. Casey*, 1992, 112 S.Ct. 2791, 120 L.Ed.2d 674, on remand 978 F.2d 74,

on remand 812 F.Supp. 541, on remand 822 F.Supp. 227.

Judicial review; statute preamble finding human life begins at conception, see *Webster v. Reproductive Health Services*, 1989, 109 S.Ct. 3040, 492 U.S. 490, 106 L.Ed.2d 410.

**145.414. Abortion not mandatory****United States Supreme Court**

Due process, abortion, use of public employees or facilities, see *Webster v. Reproductive Health Services*, 1989, 109 S.Ct. 3040, 492 U.S. 490, 106 L.Ed.2d 410.

**145.421. Human conceptus, experimentation, research or sale; definitions****United States Supreme Court**

Due process, viability testing of fetuses, state's interest in protecting potential human life, see *Webster v. Reproductive Health Services*, 1989, 109 S.Ct. 3040, 492 U.S. 490, 106 L.Ed.2d 410.

**145.422. Experimentation or sale****United States Supreme Court**

Due process, viability testing of fetuses, state's interest in protecting potential human life, see *Webster v. Reproductive Health Services*, 1989, 109 S.Ct. 3040, 492 U.S. 490, 106 L.Ed.2d 410.

**145.424. Prohibition of tort actions****Law Review Commentaries**

Injury of birth: Minnesota's statutory prohibition of postconception negligence actions. 14 *Wm.Mitchell L.Rev.* 701 (1988).

Minnesota's variable approach to state constitutional claims. Rita Coyle DeMeules, 17 *Wm.Mitchell L.Rev.* 163 (1991).

**Notes of Decisions****Wrongful birth 2****2. Wrongful birth**

Father, who had been below age of consent at time of conception of child, could not seek reim-

bursement from mother for his child support liability in wrongful birth action; father alleged that mother acted negligently by having sexual intercourse with minor. *Jevning v. Cichos*, App.1993, 499 N.W.2d 515.

**145.43. Hearing aids; restrictions on sales**

Subd. 1. Renumbered 153A.19, subd. 1 in St. 1992.

Subd. 1a. Renumbered 153A.19, subd. 2 in St. 1992.

*[See main volume for 2 and 3]*

## N.D. Cent. Code § 14-02.2 (1991)

### 14-02.1-11 DOMESTIC RELATIONS AND PERSONS

Source: S.L. 1975, ch. 124, § 1.

**14-02.1-11. General penalty.** A person violating any provision of this chapter for which another penalty is not specifically prescribed is guilty of a class A misdemeanor. Any person willfully violating a rule or regulation promulgated under this chapter is guilty of an infraction.

Source: S.L. 1975, ch. 124, § 1.

**14-02.1-12. Short title.** This chapter may be cited as the North Dakota Abortion Control Act.

Source: S.L. 1975, ch. 124, § 1.

**Note.**

Section 3 of chapter 124, S.L. 1975, provided: "Savings Clause. If any section, sub-

section, subdivision, sentence, or clause of this Act is for any reason held to be unconstitutional, such decision shall not affect the validity of the remaining portions of the Act."

## CHAPTER 14-02.2

### FETAL EXPERIMENTATION

**Section**

14-02.2-01. Live fetal experimentation —  
Penalty.

14-02.2-02. Experimentation on dead fetus  
— Use of fetal organs or tissue

for transplantation or experimentation — Sale of fetus or fetal organs or tissue — Penalty.

#### **14-02.2-01. Live fetal experimentation — Penalty.**

1. A person may not use any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory, research, or other kind of experimentation. This section does not prohibit procedures incident to the study of a human fetus while it is in its mother's womb, provided that in the best medical judgment of the physician, made at the time of the study, the procedures do not substantially jeopardize the life or health of the fetus, and provided the fetus is not the subject of a planned abortion. In any criminal proceeding the fetus is conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the study, that she was not planning an abortion.
2. A person may not use a fetus or newborn child, or any tissue or organ thereof, resulting from an induced abortion in animal or human research, experimentation, or study, or for animal or human transplantation.
3. This section does not prohibit or regulate diagnostic or remedial procedures, the purpose of which is to determine the life or health of the fetus involved or to preserve the life or health of the fetus involved, or of the mother involved.

4. A fetus is a live fetus for the purposes of this section when, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development.
5. Any person violating this section is guilty of a class A felony.

Source: S.L. 1975, ch. 125, § 1; 1989, ch. 173, § 1.

**14-02.2-02. Experimentation on dead fetus — Use of fetal organs or tissue for transplantation or experimentation — Sale of fetus or fetal organs or tissue — Penalty.**

1. An experimentation may not knowingly be performed upon a dead fetus resulting from an occurrence other than an induced abortion unless the consent of the mother has first been obtained; provided, however, that the consent is not required in the case of a routine pathological study. In any criminal proceeding, consent is conclusively presumed to have been granted for the purposes of this section by a written statement, signed by the mother who is at least eighteen years of age, to the effect that she consents to the use of her fetus for scientific, laboratory, research, or other kind of experimentation or study. Such written consent constitutes lawful authorization for the transfer of the dead fetus.
2. A person may not use a fetus or fetal organs or tissue resulting from an induced abortion in animal or human research, experimentation, or study, or for animal or human transplantation except for diagnostic or remedial procedures, the purpose of which is to determine the life or health of the fetus or to preserve the life or health of the fetus or mother, or pathological study.
3. A person may not perform or offer to perform an abortion where part or all of the consideration for the abortion is that the fetal organs or tissue may be used for animal or human transplantation, experimentation, or research or study.
4. A person may not knowingly sell, transfer, distribute, give away, accept, use, or attempt to use any fetus or fetal organs or tissue for a use that is in violation of this section. For purposes of this section, the word "fetus" includes also an embryo or neonate.
5. Violation of this section by any person is a class C felony.

Source: S.L. 1975, ch. 125, § 2; 1989, ch. 173, § 2. statutes making it a criminal offense to mistreat or wrongfully dispose of a dead body, 81 ALR 3d 1071.

**Collateral References.**

Validity, construction, and application of

N.D. Cent. Code §§ 14-02.1-01, -02 (1991)

ABORTION CONTROL ACT

14-02.1-01

CHAPTER 14-02.1

ABORTION CONTROL ACT

Section	Section
14-02.1-01. Purpose.	14-02.1-05. Preserving life of a viable child — Penalty.
14-02.1-02. Definitions.	14-02.1-06. Soliciting abortions.
14-02.1-02.1. Printed information.	14-02.1-07. Records required — Reporting of practice of abortion.
14-02.1-03. Consent to abortion — Notification requirements.	14-02.1-07.1. Forms.
14-02.1-03.1. Parental consent or judicial authorization for abortion of unmarried minor — Statement of intent.	14-02.1-08. Protection of viable fetus born alive — Penalty.
14-02.1-03.2. Civil damages for performance of abortions without informed consent.	14-02.1-09. Humane disposal of nonviable fetus.
14-02.1-03.3. Privacy of woman upon whom an abortion is performed or attempted.	14-02.1-10. Concealing stillbirth or death of infant — Penalty.
14-02.1-04. Limitations on the performance of abortions — Penalty.	14-02.1-11. General penalty.
	14-02.1-12. Short title.

**14-02.1-01. Purpose.** The purpose of this chapter is to protect unborn human life and maternal health within present constitutional limits. It reaffirms the tradition of the state of North Dakota to protect every human life whether unborn or aged, healthy or sick.

**Source:** S.L. 1975, ch. 124, § 1.

**Cross-References.**

Limitation of abortion, see chapter 14-02.3.

**DECISIONS UNDER PRIOR LAW**

**Constitutionality of State Abortion Statutes.**

State abortion statutes prohibiting abortions at any stage of pregnancy except to save the life of the mother were unconstitutional under the due process clause of the fourteenth amendment of the United States Constitution, and during first trimester of pregnancy the attending physician, in consultation with the patient, was free to determine that pregnancy should be terminated and to effectuate an abortion, without regulation or interference by the state. *Roe v. Wade* (1973) 410 US 113, 35 LEd 2d 147, 93 Sup Ct 705.

The former North Dakota Abortion Law violated the due process clause of the fourteenth amendment to the United States Constitution in that it excepted from criminality only abortions to save the life of the mother, without regard to the stage of pregnancy, and without recognition of the other interests involved. *Leigh v. Olson* (1974) 385 FSupp 255.

**Standing to Challenge Law.**

Although no actual abortion had been per-

formed upon or denied to any pregnant woman, physician had standing to challenge abortion law which interfered with his practice of medicine and his relationship with his patients, and he should not be required to risk becoming a test case in a criminal prosecution. *Leigh v. Olson* (1974) 385 FSupp 255.

**Viability.**

A quick fetus and a viable fetus are not the same, and only after a fetus becomes viable or potentially able to live outside the womb did the state have the right to regulate or proscribe abortion; the question of whether or not the fetus is, in fact, viable should be left to the medical judgment of the physician. *Leigh v. Olson* (1974) 385 FSupp 255.

Although the fetus quickens or begins to move in the womb after about sixteen weeks of pregnancy, it is not until the fetus becomes viable, or potentially able to live outside the womb, that the protection of the life of the unborn child becomes a compelling state interest for the regulation of abortion. *Leigh v. Olson* (1974) 385 FSupp 255.

**Collateral References.**

Medical malpractice in performance of legal abortion, 69 ALR 4th 875.

**14-02.1-02. Definitions.** As used in this chapter:

1. "Abortion" means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead embryo or fetus.
2. "Abortion facility" means a clinic, ambulatory surgical center, physician's office, or any other place or facility in which abortions are performed, other than a hospital.
3. "Hospital" means an institution licensed by the state department of health and consolidated laboratories under chapter 23-16, and any hospital operated by the United States or this state.
4. "Infant born alive" or "live born child" means a born child which exhibits either heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles or pulsation of the umbilical cord if still attached to the child.
5. "Informed consent" means voluntary consent to abortion by the woman upon whom the abortion is to be performed provided that:
  - a. The woman is told the following by the physician who is to perform the abortion, by the referring physician, or by the physician's agent, at least twenty-four hours before the abortion:
    - (1) The name of the physician who will perform the abortion;
    - (2) The particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility;
    - (3) The probable gestational age of the unborn child at the time the abortion is to be performed; and
    - (4) The medical risks associated with carrying her child to term.
  - b. The woman is informed, by the physician or the physician's agent, at least twenty-four hours before the abortion:
    - (1) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care;
    - (2) That the father is liable to assist in the support of her child, even in instances in which the father has offered to pay for the abortion; and
    - (3) That she has the right to review the printed materials described in section 14-02.1-02.1. The physician or the physician's agent shall orally inform the woman the materials have been provided by the state of North Dakota and that they describe the unborn child and list agencies that offer alternatives to abortion. If the woman chooses to view the materials, copies of them must be furnished to her. The physician and the physician's agent may disassociate themselves from the materials and may comment or refrain from comment on them, as they choose.
  - c. The woman certifies in writing, prior to the abortion, that the information described in subdivisions a and b has been furnished

to her, and that she has been informed of her opportunity to review the information referred to in paragraph 3 of subdivision b.

- d. Prior to the performance of the abortion, the physician who is to perform or induce the abortion or the physician's agent receives a copy of the written certification prescribed by subdivision c.
6. "Licensed physician" means a person who is licensed to practice medicine or osteopathy under chapter 43-17, or a physician practicing in the armed services of the United States, or in the employ of the United States.
7. "Medical emergency" means that condition which, on the basis of the physician's best clinical judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the death of the mother or for which a twenty-four hour delay will create grave peril of immediate and irreversible loss of major bodily function.
8. "Probable gestational age of the unborn child" means what, in the judgment of the attending physician, will with reasonable probability be the gestational age of the unborn child at the time the abortion is planned to be performed.
9. "Viable" means the ability of a fetus to live outside the mother's womb, albeit with artificial aid.

**Source:** S.L. 1975, ch. 124, § 1; 1979, ch. 191, §§ 1, 2; 1991, ch. 141, §§ 1, 2.

**Note.**

Former subsection 7 was renumbered as subsection 9 upon the enactment of present subsections 7 and 8 in 1991.

**DECISIONS UNDER PRIOR LAW**

**Constitutionality.**

Informed consent provision, former subdivision 4c, that physician must disclose to all patients the "probable anatomical and physiological characteristics of the unborn child at the time the abortion is to be performed" is an impermissible intrusion by the state into the physician-patient relationship which unduly burdens the woman's constitutional right to decide in consultation with her physician, free from governmental interference, whether to have an abortion in the first trimester; therefore, former subdivision 4c is unconstitutional. *Leigh v. Olson* (1980) 497 FSupp 1340.

Informed consent provision, former subdivision 4d, that physician must disclose to all patients "the immediate and long-term physical dangers of abortion, psychological trauma resulting from abortion, sterility and increases in the incidence of premature births, tubal pregnancies and stillbirths in

subsequent pregnancies, as compared to the dangers in carrying the pregnancy to term" is an impermissible intrusion by the state into the physician-patient relationship which unduly burdens the woman's constitutional right to decide in consultation with her physician, free from governmental interference, whether to have an abortion in the first trimester; therefore, former subdivision 4d was unconstitutional. *Leigh v. Olson* (1980) 497 FSupp 1340.

Informed consent provision, former subdivision 4f, that physician must disclose to all patients the "alternatives to abortion such as childbirth and adoption and information concerning public and private agencies that will provide the woman with economic and other assistance and encouragement to carry her child to term including, if the woman so requests, a list of the agencies and the services available from each" does not unduly burden the woman's constitutional right to obtain an abortion in the first trimester and is not unconstitutionally vague but is a legitimate attempt by the state to encourage childbirth over abortion. *Leigh v. Olson* (1980) 497 FSupp 1340.

**Collateral References.**

Abortion ⇌ 1.

1 Am. Jur. 2d, Abortion, §§ 1, 1.5, 2.

1 C.J.S. Abortion, §§ 1, 2.



SURROGACY

168-B:15

**In Vitro Fertilization and Preembryo Transfer**

**168-B:13 Eligibility.** In vitro fertilization and preembryo transfer shall be performed in accordance with rules adopted by the division of public health services and shall be available only to a woman:

- I. Who is 21 years of age or older;
- II. Who has been medically evaluated and the results, documented in accordance with rules adopted by the division of public health services, demonstrate the medical acceptability of the woman to undergo the in vitro fertilization or preembryo transfer procedure;
- III. Who receives counseling pursuant to RSA 168-B:18, and provides written certification of the counseling and evaluation to the health care provider performing the in vitro fertilization or preembryo transfer procedure; and
- IV. Whose husband, if the recipient is married, receives appropriate counseling, pursuant to RSA 168-B:18, and:
  - (a) Successfully completes the medical evaluation, if he is the gamete donor in the in vitro fertilization or preembryo transfer procedure;
  - (b) Provides written certification of the nonmedical counseling and any evaluation to the health care provider performing the in vitro fertilization or preembryo transfer procedure; and
  - (c) Indicates, by a writing, acceptance of the legal rights and responsibilities of parenthood for any resulting child, unless the husband contributes his sperm for the in vitro fertilization or preembryo transfer procedure.

HISTORY

Source. 1990, 87:2, eff. Jan. 1, 1991.

CROSS REFERENCES

Medical evaluation, see RSA 168-B:19.

**168-B:14 Gamete Donors.** No gamete shall be used in an in vitro fertilization or preembryo transfer procedure, unless the gamete donor has been medically evaluated and the results, documented in accordance with rules adopted by the division of public health services, demonstrate the medical acceptability of the person as a gamete donor.

HISTORY

Source. 1990, 87:2, eff. Jan. 1, 1991.

CROSS REFERENCES

Medical evaluation, see RSA 168-B:19.

**168-B:15 Restrictions on Use of Preembryos.**

- I. No preembryo shall be maintained ex utero in the noncryo-preserved state beyond 14 days post-fertilization development.
- II. No preembryo that has been donated for use in research shall be transferred to a uterine cavity.

§ 3216. Fetal experimentation

(a) **Unborn or live child.**—Any person who knowingly performs any type of nontherapeutic experimentation or nontherapeutic medical procedure (except an abortion as defined in this chapter) upon any unborn child, or upon any child born alive during the course of an abortion, commits a felony of the third degree. “Nontherapeutic” means that which is not intended to preserve the life or health of the child upon whom it is performed.

(b) **Dead child.**— The following standards govern the procurement and use of any fetal tissue or organ which is used in animal or human transplantation, research or experimentation:

(1) No fetal tissue or organs may be procured or used without the written consent of the mother. No consideration of any kind for such consent may be offered or given. Further, if the tissue or organs are being derived from abortion, such consent shall be valid only if obtained after the decision to abort has been made.

(2) No person who provides the information required by section 3205 (relating to informed consent) shall employ the possibility of the use of aborted fetal tissue or organs as an inducement to a pregnant woman to undergo abortion except that payment for reasonable expenses occasioned by the actual retrieval, storage, preparation and transportation of the tissues is permitted.

(3) No remuneration, compensation or other consideration may be paid to any person or organization in connection with the procurement of fetal tissue or organs.

(4) All persons who participate in the procurement, use or transplantation of fetal tissue or organs, including the recipients of such tissue or organs, shall be informed as to whether the particular tissue or organ involved was procured as a result of either:

- (i) stillbirth;
- (ii) miscarriage;
- (iii) ectopic pregnancy;
- (iv) abortion; or
- (v) any other means.

(5) No person who consents to the procurement or use of any fetal tissue or organ may designate the recipient of that tissue or organ, nor shall any other person or organization act to fulfill that designation.

(6) The department may assess a civil penalty upon any person who procures, sells or uses any fetal tissue or organs in violation of this section or the regulations issued thereunder. Such civil penalties may not exceed \$5,000 for each separate violation. In assessing such penalties, the department shall give due consideration to the gravity of the violation, the good faith of the violator and the history of previous violations. Civil penalties due under this paragraph shall be paid to the department for deposit in the State Treasury and may be enforced by the department in the Commonwealth Court.

(c) **Construction of section.**—Nothing in this section shall be construed to condone or prohibit the performance of diagnostic tests while the unborn child is in utero or the performance of pathological examinations on an aborted child. Nor shall anything in this section be construed to condone or prohibit the performance of in vitro fertilization and accompanying embryo transfer.

As amended 1989, Nov. 17, P.L. 592, No. 64, § 4, effective in 60 days.

#### Historical and Statutory Notes

##### 1989 Legislation

The 1989 amendment rewrote the section.

Section 6 of Act 1989, Nov. 17, P.L. 592, No. 64, provides:

"The provisions of this act are severable. If any word, phrase or provision of this act or its

application to any person or circumstance is held invalid, the invalidity shall not affect any other word, phrase or provision or application of this act which can be given effect without the invalid word, phrase, provision or application."

#### § 3217. Civil penalties

Any physician who knowingly violates any of the provisions of section 3204 (relating to medical consultation and judgment) or 3205 (relating to informed consent) shall, in addition to any other penalty prescribed in this chapter, be civilly liable to his patient for any damages caused thereby and, in addition, shall be liable to his patient for punitive damages in the amount of \$5,000, and the court shall award a prevailing plaintiff a reasonable attorney fee as part of costs.

As amended 1988, March 25, P.L. 262, No. 31, § 10, effective in 30 days; 1989, Nov. 17, P.L. 592, No. 64, § 4, effective in 60 days.

#### Historical and Statutory Notes

##### 1988 Legislation

The 1988 amendment increased the punitive damage limit from one thousand dollars to five thousand dollars.

##### 1989 Legislation

The 1989 amendment added the requirement that the court award a prevailing plaintiff a reasonable attorney fee.

Section 6 of Act 1989, Nov. 17, P.L. 592, No. 64, provides:

"The provisions of this act are severable. If any word, phrase or provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect any other word, phrase or provision or application of this act which can be given effect without the invalid word, phrase, provision or application."

#### § 3218. Criminal penalties

(a) **Application of chapter.**—Notwithstanding any other provision of this chapter, no criminal penalty shall apply to a woman who violates any provision of this chapter solely in order to perform or induce or attempt to perform or induce an abortion upon herself. Nor shall any woman who undergoes an abortion be found guilty of having committed an offense, liability for which is defined under section 306 (relating to liability for conduct of another; complicity) or Chapter 9 (relating to inchoate crimes), by reason of having undergone such abortion.

(b) **False statement, etc.**—A person commits a misdemeanor of the second degree if, with intent to mislead a public servant in performing his official function under this chapter, such person:

- (1) makes any written false statement which he does not believe to be true; or
- (2) submits or invites reliance on any writing which he knows to be forged, altered or otherwise lacking in authenticity.

(c) **Statements "under penalty."**—A person commits a misdemeanor of the third degree if such person makes a written false statement which such person does not believe to be true on a statement submitted as required under this chapter, bearing notice to the effect that false statements made therein are punishable.

(d) **Perjury provisions applicable.**—Section 4902(c) through (f) (relating to perjury) apply to subsections (b) and (c).

As amended 1988, March 25, P.L. 262, No. 31, § 10, effective in 30 days; 1989, Nov. 17, P.L. 592, No. 64, § 4, effective in 60 days.

## CHAPTER 32

### ABORTION

#### Section

- 3208.1. Commonwealth interference prohibited.  
3209. Spouse notice.

### Pennsylvania Code References

Ambulatory gynecological surgery in hospitals and clinics, see 28 Pa. Code § 29.31 et seq.

### Law Review Commentaries

Toward constitutional abortion control legislation: Pennsylvania approach. (1983) 87 Dick. L.Rev. 373.

### WESTLAW Electronic Research

See WESTLAW Electronic Research Guide following the Preface.

### § 3201. Short title of chapter

### Notes of Decisions

#### 1. Validity

American College of Obstetricians and Gynecologists, *Pennsylvania Section v. Thornburgh*, 552 F.Supp. 791, D.C.1982 [main volume] remanded 737 F.2d 283, affirmed 106 S.Ct. 2169, 476 U.S. 747, 90 L.Ed.2d 779, stay granted 613 F.Supp. 656.

#### 3. Standing

American College of Obstetricians and Gynecologists, *Pennsylvania Section v. Thornburgh*, 552 F.Supp. 791, D.C.1982 [main volume] remanded 737 F.2d 283, affirmed 106 S.Ct. 2169, 476 U.S. 747, 90 L.Ed.2d 779, stay granted 613 F.Supp. 656.

## § 3202. Legislative intent

## Notes of Decisions

Validity 1

552 F.Supp. 791, D.C.1982 [main volume] remanded 737 F.2d 283, affirmed 106 S.Ct. 2169, 476 U.S. 747, 90 L.Ed.2d 779, stay granted 613 F.Supp. 656.

## 1. Validity

American College of Obstetricians and Gynecologists, Pennsylvania Section v. Thornburgh.

## § 3203. Definitions

The following words and phrases when used in this chapter shall have, unless the context clearly indicates otherwise, the meanings given to them in this section:

*[See main volume for other definitions]*

**"Fertilization"** and **"conception."** Each term shall mean the fusion of a human spermatozoon with a human ovum.

As amended 1989, Nov. 17, P.L. 592, No. 64, § 1, effective in 60 days.

*[See main volume for other definitions]*

**"Gestational age."** The age of the unborn child as calculated from the first day of the last menstrual period of the pregnant woman.

Added 1989, Nov. 17, P.L. 592, No. 64, § 1, effective in 60 days.

*[See main volume for other definitions]*

**"Medical emergency."** That condition which, on the basis of the physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of major bodily function.

As amended 1988, March 25, P.L. 262, No. 31, § 3, effective in 30 days.

*[See main volume for other definitions]*

**"Physician."** Any person licensed to practice medicine in this Commonwealth. The term includes medical doctors and doctors of osteopathy.

As amended 1988, March 25, P.L. 262, No. 31, § 3, effective in 30 days.

**"Pregnancy"** and **"pregnant."** Each term shall mean that female reproductive condition of having a developing fetus in the body and commences with fertilization.

As amended 1989, Nov. 17, P.L. 592, No. 64, § 1, effective in 60 days.

*[See main volume for other definitions]*

**"Unborn child"** and **"fetus."** Each term shall mean an individual organism of the species homo sapiens from fertilization until live birth.

As amended 1989, Nov. 17, P.L. 592, No. 64, § 1, effective in 60 days.

*[See main volume for other definitions]*

## Historical and Statutory Notes

## 1988 Legislation

The 1988 amendment rewrote the definition of "medical emergency" and added the definition of "physician".

A former definition of "physician" was repealed by 1984, Dec. 18, P.L. 1057, No. 207, § 2, imd. effective, retroactively to June 11, 1982.

## 1989 Legislation

The 1989 amendment rewrote the definitions of "fertilization", "pregnancy", and "unborn

child", and added the definition of "gestational age".

Section 6 of Act 1989, Nov. 17, P.L. 592, No. 64, provides:

"The provisions of this act are severable. If any word, phrase or provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect any other word, phrase or provision or application of this act which can be given effect without the invalid word, phrase, provision or application."

**18 Pa. Cons. Stat. Ann. § 3216 (Purdon, n.d.)**

**§ 3216. Fetal experimentation**

(a) **Unborn or live child.**—Any person who knowingly performs any type of nontherapeutic experimentation upon any unborn child, or upon any child born alive during the course of an abortion, commits a felony of the third degree. “Nontherapeutic” means that which is not intended to preserve the child’s life or health.

(b) **Dead child.**—Experimentation upon children who have died during the course of an abortion may be conducted only upon the written consent of the mother: Provided, That no consideration for such consent is offered or given. Any person who knowingly violates this subsection commits a misdemeanor of the first degree.

1982, June 11, P.L. 476, No. 138, § 1, effective in 180 days.

**Historical Note**

**Prior Laws:**

1974, Sept. 10, P.L. 639, No. 209, § 5  
(35 P.S. § 6605).

**Library References**

Abortion and Birth Control Ⓒ1.  
C.J.S. Abortion §§ 3 to 11.

**§ 3217. Civil penalties**

Any physician who knowingly violates any of the provisions of section 3204 (relating to medical consultation and judgment) or 3205 (relating to informed consent) shall, in addition to any other penalty prescribed in this chapter, be civilly liable to his patient for any damages caused thereby and, in addition, shall be liable to his patient for punitive damages in the amount of \$1,000.

1982, June 11, P.L. 476, No. 138, § 1, effective in 180 days.

**Library References**

Abortion and Birth Control Ⓒ16.  
C.J.S. Abortion §§ 41 to 43.

**§ 3218. Criminal penalties**

Notwithstanding any other provision of this chapter, no criminal penalty shall apply to a woman who violates any provision of this chapter solely in order to perform or induce or attempt to perform or induce an abortion upon herself.

1982, June 11, P.L. 476, No. 138, § 1, effective in 180 days.

**Library References**

Abortion and Birth Control Ⓒ15.  
C.J.S. Abortion §§ 40, 46.

CHAPTER 54  
EXPERIMENTATION ON HUMAN FETUSES

SECTION.	SECTION.
11-54-1. Experimentation on human fetuses.	11-54-2. Penalties.

**11-54-1. Experimentation on human fetuses.** — (a) No person shall use any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory research, or other kind of experimentation. This section shall not prohibit procedures incident to the study of a human fetus while it is in its mother's womb, provided that in the best medical judgment of the physician, made at the time of the study said procedures do not substantially jeopardize the life or health of the fetus, and provided said fetus is not the subject of a planned abortion. In any criminal proceeding the fetus shall be conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the study that she was not planning an abortion.

(b) This section shall not prohibit or regulate diagnostic or remedial procedures the purpose of which is to determine or to preserve the life or health of the fetus involved or the mother involved.

(c) A fetus is a live fetus for purposes of this section when, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development.

(d) No experimentation may knowingly be performed upon a dead fetus unless the consent of its mother has first been obtained, provided however that such consent shall not be required in the case of a routine pathological study. In any criminal proceeding, consent shall be conclusively presumed to have been granted for the purposes of this section by a written statement, signed by the mother, who is at least eighteen (18) years of age, to the effect that she consents to the use of her fetus for scientific, laboratory, research, or other kind of experimentation or study; such written consent shall constitute lawful authorization for the transfer of the dead fetus.

(e) No person shall perform or offer to perform an abortion where part or all of the consideration for said performance is that the fetal remains may be used for experimentation or other kinds of research or study.

(f) No person shall knowingly sell, transfer, distribute, or give away any fetus for a use which is in violation of the provisions of this section. For purposes of this section, the word "fetus" shall include an embryo or neonate.

**History of Section.**

P.L. 1981, ch. 231, § 1.

**11-54-2. Penalties.** — Any person who performs any of the acts prohibited by this chapter shall be guilty of a felony and shall be punished by a fine of at least one thousand dollars (\$1,000), or shall be imprisoned for a period of at least one (1) year, or both.

**History of Section.**

P.L. 1981, ch. 231, § 1.

**Utah Code Ann. § 76-7-310 (1990)**

76-7-309

**CRIMINAL CODE**

**COLLATERAL REFERENCES**

**A.L.R.** — Medical malpractice in performance of legal abortion, 69 A.L.R.4th 875.

**76-7-309. Pathologist's report.**

Any human tissue removed during an abortion shall be submitted to a pathologist who shall make a report, including, but not limited to whether there was a pregnancy, and if possible, whether the pregnancy was aborted by evacuating the uterus.

**History:** C. 1953, 76-7-309, enacted by L. 1974, ch. 33, § 9.

**76-7-310. Experimentation with unborn children prohibited — Testing for genetic defects.**

Live unborn children may not be used for experimentation, but when advisable, in the best medical judgment of the physician, may be tested for genetic defects.

**History:** C. 1953, 76-7-310, enacted by L. 1974, ch. 33, § 10.

**76-7-311. Selling and buying unborn children prohibited.**

Selling, buying, offering to sell and offering to buy unborn children is prohibited.

**History:** C. 1953, 76-7-311, enacted by L. 1974, ch. 33, § 11.

**76-7-312. Intimidation or coercion of person to obtain abortion prohibited.**

No person shall intimidate or coerce in any way any person to obtain an abortion.

**History:** C. 1953, 76-7-312, enacted by L. 1974, ch. 33, § 12.

**76-7-313. Physician's report to department of health.**

In order for the state department of health to maintain necessary statistical information and ensure enforcement of the provisions of this part, any physician performing an abortion must obtain and record in writing: the age of the pregnant woman; her marital status and county of residence; the number of previous abortions performed on her; the hospital or other facility where performed; the weight in grams of the unborn child aborted, if it is possible to ascertain; the pathological description of the unborn child; the given menstrual age of the unborn child; the measurements, if possible to ascertain; and the medical procedure used. This information, and a copy of the pathologist's



report, as required in Section 76-7-309, together with an affidavit that the required consent was obtained pursuant to Section 76-7-305 and a certificate by the physician that the unborn child was or was not capable of survival outside of the mother's womb, must be filed by the physician with the state department of health within 10 days after the abortion. All information supplied to the state department of health shall be confidential and privileged pursuant to chapter 25, Title 26.

**History:** C. 1953, 76-7-313, enacted by L. 1981, ch. 126, § 57.

**Repeals and Reenactments.** — Laws 1981, ch. 126, § 57 repealed former § 76-7-313 (L.

1974, ch. 33, § 13), relating to physician's report to division of health, and enacted present § 76-7-313.

#### COLLATERAL REFERENCES

**Utah Law Review.** — Constitutional Law, Substantive Due Process, Abortion, Reasonable Statutory Recordkeeping and Reporting

Requirements Upheld, 1976 B.Y.U. L. Rev. 977.

### 76-7-314. Violations of abortion laws — Classifications.

(1) Any person who performs, procures or supplies the means for an abortion other than authorized by this chapter [part] is guilty of a felony of the second degree.

(2) A violation of Section 76-7-307, 76-7-308, 76-7-310, 76-7-311, or 76-7-312 is a felony of the third degree.

(3) A violation of any other provision in this act [part] is a class A misdemeanor.

**History:** C. 1953, 76-7-314, enacted by L. 1974, ch. 33, § 14.

**Cross-References.** — Corroboration unnec-

essary as to testimony of accomplice, § 77-17-7.

#### NOTES TO DECISIONS

##### ANALYSIS

Corroboration.

Evidence.

—Intent.

Indictment.

Operation to save life of woman.

Pleading and proof.

Pregnancy as element of crime.

Procuring abortion.

**Corroboration.**

In abortion prosecution, testimony of mother of prosecutrix that she accompanied prosecutrix to defendant's office and saw him use instrument for purpose of producing abortion was sufficient to corroborate testimony of prosecutrix. *State v. Cragun*, 85 Utah 149, 38 P.2d 1071 (1934).

**Evidence.**

—Intent.

For purpose of proving that operation was, in

fact, criminal, and to show intent of accused, state could show that similar operations were performed upon other pregnant women. *State v. McCurtain*, 52 Utah 63, 172 P. 481 (1918).

**Indictment.**

Charge in complaint and information that defendant did specified things with intent to procure "miscarriage" of pregnant woman, instead of with intent to procure "abortion," was within terms of former statute. *State v. Crook*, 16 Utah 212, 51 P. 1091 (1898).

**Operation to save life of woman.**

Testimony of expert medical witnesses could be introduced on question of necessity of abortion to save life of deceased pregnant woman. *State v. McCoy*, 15 Utah 136, 49 P. 420 (1897).

In prosecution for abortion, fact that woman was unmarried and that defendant had illicit sexual intercourse with her was insufficient to show that operation was not necessary to save woman's life. *State v. Wells*, 35 Utah 400, 100

**History:** C. 1953, 76-7-307, enacted by L. 1974, ch. 33, § 7; 1991 (1st S.S.), ch. 2, § 5.

**Amendment Notes.** — The 1991 (1st S.S.) amendment, effective April 29, 1991, substituted "that unborn child" for "an unborn child"

and "to prevent grave damage to her medical health" for "to save her life or prevent serious and permanent damage to her health" in the second sentence.

## NOTES TO DECISIONS

## ANALYSIS

**Constitutionality.**  
Cited.

rational relationship to the legitimate state interest in preservation of viable fetal life. *Jane L. v. Bangerter*, 809 F. Supp. 865 (D. Utah 1992).

**Constitutionality.**

This section is constitutional, for it bears a

Cited in *Jane L. v. Bangerter*, 794 F. Supp. 1528, 794 F. Supp. 1537 (D. Utah 1992).

### 76-7-308. Medical skills required to preserve life of unborn child.

Consistent with the purpose of saving the life of the woman or preventing grave damage to the woman's medical health, the physician performing the abortion must use all of his medical skills to attempt to promote, preserve and maintain the life of any unborn child sufficiently developed to have any reasonable possibility of survival outside of the mother's womb.

**History:** C. 1953, 76-7-308, enacted by L. 1974, ch. 33, § 8; 1991 (1st S.S.), ch. 2, § 6.

**Amendment Notes.** — The 1991 (1st S.S.)

amendment, effective April 29, 1991, substituted "grave" for "serious and permanent" and inserted "medical" in the first phrase.

## NOTES TO DECISIONS

**Constitutionality.**

This section is constitutional, for it bears a rational relationship to the legitimate state

interest in preservation of viable fetal life. *Jane L. v. Bangerter*, 809 F. Supp. 865 (D. Utah 1992).

### 76-7-310. Experimentation with unborn children prohibited — Testing for genetic defects.

## NOTES TO DECISIONS

**Constitutionality.**

This section is not unconstitutionally vague; it does not impinge upon constitutionally pro-

tected privacy interests; and it is facially valid as a matter of law. *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).

### 76-7-314. Violations of abortion laws — Classifications.

- (1) (a) Any person who intentionally performs an abortion other than authorized by this part is guilty of a felony of the third degree.
- (b) Notwithstanding any other provision of law, a woman who seeks to have or obtains an abortion for herself is not criminally liable.
- (2) A violation of Section 76-7-307, 76-7-308, 76-7-310, 76-7-311, or 76-7-312 is a felony of the third degree.
- (3) A violation of any other provision of this part is a class A misdemeanor.

**History:** C. 1953, 76-7-314, enacted by L. 1974, ch. 33, § 14; 1991, ch. 1, § 4; 1991 (1st S.S.), ch. 2, § 7.

**Amendment Notes.** — The 1991 amendment, effective April 29, 1991, in Subsection (1) substituted “part” for “chapter” and “third degree” for “second degree” in the first sentence and added the second and third sentences; and in Subsection (3) substituted “part” for “act.”

The 1991 (1st S.S.) amendment, effective April 29, 1991, subdivided Subsection (1); in Subsection (1)(a) substituted “intentionally performs” for “performs, procures or supplies the means for” and deleted the former second sentence, which read “For purposes of this

subsection a person who procures an abortion does not include”; and substituted the present provisions of Subsection (1)(b) for “a woman who is seeking to have an abortion performed on herself. A woman who is seeking to have an abortion performed on herself is not criminally liable under Section 76-2-202.”

**Compiler’s Notes.** — Laws 1991 (1st S.S.), ch. 2, which amended this section, provides in § 9: “The provisions of this act supersede any conflicting provisions contained in S.B. 23, Chapter 1, Laws of Utah 1991 [which also amended this section], and H.B. 257, Chapter 288, Laws of Utah 1991.”

#### NOTES TO DECISIONS

##### ANALYSIS

##### Liability.

##### — Accessories.

##### Liability.

Because this section limits liability for an illegal abortion to “any person who intentionally performs an abortion other than authorized by this part . . .,” it follows that a woman who seeks or obtains an abortion does not risk criminal prosecution. *Jane L. v. Bangerter*, 794 F. Supp. 1528, 794 F. Supp. 1537 (D. Utah 1992).

##### — Accessories.

Because accessorial liability is only predi-

cated upon aiding, encouraging, or soliciting one who engages in conduct that constitutes an offense, counselors, clergy, or doctors who counsel a woman on abortion options are not violating the law. *Jane L. v. Bangerter*, 794 F. Supp. 1528, 794 F. Supp. 1537 (D. Utah 1992).

If counselors go so far as to solicit a doctor to perform an abortion against the doctor’s professional judgment, there may be liability under the Utah accessorial liability statute. *Jane L. v. Bangerter*, 794 F. Supp. 1528, 794 F. Supp. 1537 (D. Utah 1992).

### 76-7-315. Exceptions to certain requirements in serious medical emergency.

When due to a serious medical emergency, time does not permit compliance with Section 76-7-302, Subsection 76-7-304(2) or Subsection 76-7-305(2), the provisions of those sections do not apply.

**History:** C. 1953, 76-7-315, enacted by L. 1974, ch. 33, § 15; 1991, ch. 1, § 5.

**Amendment Notes.** — The 1991 amendment, effective April 29, 1991, substituted all of

the present language following “compliance” for “with Section 76-7-302(2), 76-7-304(2) or 76-7-305(2), the provisions of those sections shall not apply.”

#### NOTES TO DECISIONS

##### ANALYSIS

##### Constitutionality.

##### Cited.

##### Constitutionality.

This section provides the fair warning to

physicians required by the due process clause, sets clear guidelines for enforcement officials, and is therefore not void for vagueness. *Jane L. v. Bangerter*, 809 F. Supp. 865 (D. Utah 1992).

Cited in *Jane L. v. Bangerter*, 794 F. Supp. 1528, 794 F. Supp. 1537 (D. Utah 1992).

**76-7-317.1. Creation of Abortion Litigation Trust Account.**

(1) (a) There is created in the General Fund a restricted account known as the Abortion Litigation Trust Account. All money received by the state from private sources for litigation expenses connected with the defense of Senate Bill 23, passed in the 1991 Annual General Session, shall be deposited in that account.

(b) On behalf of the Abortion Litigation Trust Account, the Division of Finance may accept grants, gifts, bequests, or any money made available from any private sources to implement this section.

(2) Money shall be appropriated by the Legislature from the account to the Office of the Attorney General under Title 63, Chapter 38, Budgetary Procedures Act.

(3) The Abortion Litigation Trust Account may be used only for costs, expenses, and attorneys fees connected with the defense of the abortion law identified in Subsection (1).

(4) Any funds remaining in the abortion litigation trust account after final appellate procedures shall revert to the General Fund, to be first used to offset the monies expended by the state in connection with litigation regarding Senate Bill 23.

**History:** C. 1953, 76-7-317.1, enacted by L. 1991, ch. 288, § 2.

**Compiler's Notes.** — Senate Bill 23, cited in Subsections (1) and (4), is L. 1991, ch. 1, which enacted § 76-7-301.1 and amended §§ 76-7-

301, 76-7-302, 76-7-314, and 76-7-315.

**Effective Dates.** — Laws 1991, ch. 288 became effective on April 29, 1991, pursuant to Utah Const., Art. VI, Sec. 25.

**76-7-317.2. Finding of unconstitutionality — Revival of old law.**

If Section 76-7-302 as amended by Senate Bill 23, 1991 Annual General Session, is ever held to be unconstitutional by the United States Supreme Court, Section 76-7-302, as enacted by Chapter 33, Laws of Utah 1974, is reenacted and immediately effective.

**History:** C. 1953, 76-7-317.2, enacted by L. 1991, ch. 288, § 3.

**Effective Dates.** — Laws 1991, ch. 288

became effective on April 29, 1991, pursuant to Utah Const., Art. VI, Sec. 25.

## NOTES TO DECISIONS

## ANALYSIS

## Constitutionality.

—Due process.

—Vagueness.

## Constitutionality.

The Equal Protection Clause does not require that the Utah Abortion Act apply equally to all persons. *Jane L. v. Bangerter*, 794 F. Supp. 1537 (D. Utah 1992).

The Utah Abortion Act does not violate the Utah Equal Protection Clause by prohibiting elective abortions for the only sex capable of having abortions. *Jane L. v. Bangerter*, 794 F. Supp. 1528 (D. Utah 1992).

Subsection (3) is not rendered unconstitutional by the invalidation of Subsection (2) because, despite its incorporation of Subsections (2)(a), (d), and (e), a section of a statute may be severed from an invalidated statute if the remaining portions can stand alone and serve a legitimate purpose, as is the case of the post-viability requirements which serve to preserve the life or health of the mother. *Jane L. v. Bangerter*, 809 F. Supp. 865 (D. Utah 1992).

## —Due process.

This section, insofar as it relates to pre-viability abortions before 21 weeks gestational age, is an unconstitutional infringement on a woman's liberty interest under the Due Process Clause of the Fourteenth Amendment, as expressed by the United States Supreme Court in *Planned Parenthood v. Casey*, U.S. , 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992). *Jane L. v. Bangerter*, 809 F. Supp. 865 (D. Utah 1992).

## —Vagueness.

Subsections (2)(a), (d), and (e) of this section were not void for vagueness under Utah Const., Art. I, Secs. 1, 2, 3, 7, 25, and 27 for failing to give adequate notice of the precise nature of the prohibited conduct, even though the statute used arguably vague terms such as "necessary to save the mother's life," "grave danger to the woman's medical health," and "grave defects," since the "professional judgment" of the attending physician constitutes the measure of determining the meaning of these general terms in a particular case. *Jane L. v. Bangerter*, 794 F. Supp. 1528, 794 F. Supp. 1537 (D. Utah 1992).

## COLLATERAL REFERENCES

**Brigham Young Law Review.** — Mediating the Polar Extremes: A Guide to Post-Webster Abortion Policy, 1991 B.Y.U. L. Rev. 403.

A Legal Strategy to Overturn *Roe v. Wade* After *Webster*: Some Lessons from Lincoln, 1991 B.Y.U. L. Rev. 519.

## 76-7-304. Considerations by physician — Notice to minor's parents or guardian or married woman's husband.

## NOTES TO DECISIONS

## Constitutionality.

## —Spousal notification.

Following the United States Supreme Court's decision in *Planned Parenthood v. Casey*, U.S. , 112 S. Ct. 2791, 120 L. Ed. 2d

674 (1992), the spousal notification requirement of this section is an unconstitutional infringement upon a woman's liberty interest. *Jane L. v. Bangerter*, 809 F. Supp. 865 (D. Utah 1992).

## 76-7-305. Informed consent requirements for abortion — 24-hour wait mandatory — Emergency exception.

(1) No abortion may be performed unless a voluntary and informed written consent is first obtained by the attending physician from the woman upon whom the abortion is to be performed. Except in the case of a medical emergency, consent to an abortion is voluntary and informed if and only if:

(a) at least 24 hours prior to the abortion, the physician who is to perform the abortion, the referring physician, a registered nurse, nurse practitioner, advanced practice registered nurse, certified nurse midwife, or physician's assistant shall orally inform the woman of:

(i) the nature of the proposed procedure or treatment and of the risks and alternatives to that procedure or treatment that a reasonable patient would consider material to the decision of whether or not to undergo the abortion;

(ii) the probable gestational age of the unborn child at the time the abortion is to be performed; and

(iii) the medical risks associated with carrying her child to term;

(b) the information required to be provided to the pregnant woman under Subsection (a) is also provided by the physician who is to perform the abortion, prior to performance of the abortion, unless the attending or referring physician was the individual providing the information under Subsection (a);

(c) at least 24 hours prior to the abortion the physician who is to perform the abortion, the referring physician, or, as specifically delegated by either of those physicians, a registered nurse, licensed practical nurse, certified nurse-midwife, advanced practice registered nurse, clinical laboratory technologist, psychologist, marriage and family therapist, clinical social worker, or certified social worker has orally informed the pregnant woman that:

(i) the Department of Health publishes printed material that describes the unborn child and lists agencies that offer alternatives to abortion, and that she has a right to review that printed material, which will be provided to her free of charge if she chooses to review it;

(ii) medical assistance benefits may be available for prenatal care, childbirth, and neonatal care, and that more detailed information on the availability of that assistance is contained in the printed materials published by the Department of Health; and

(iii) the father of the unborn child is legally required to assist in the support of her child, even in instances where he has offered to pay for the abortion. In the case of rape, this information may be omitted;

(d) a copy of the printed materials has been provided to the pregnant woman if she chooses to review those materials; and

(e) the pregnant woman has certified in writing, prior to the abortion, that the information required to be provided under Subsections (a), (b), (c), and (d) was provided.

(2) When a medical emergency compels the performance of an abortion, the physician shall inform the woman prior to the abortion, if possible, of the medical indications supporting his judgment that an abortion is necessary to avert her death or to avert substantial and irreversible impairment of major bodily function.

(3) Any physician who violates the provisions of this section is guilty of unprofessional conduct as defined in Section 58-12-36, and his license for the practice of medicine and surgery shall be subject to suspension or revocation in accordance with Sections 58-12-26 through 58-12-43, Medical Practice Act.

(4) A physician is not guilty of violating this section, for failure to furnish the information described in Subsection (1), if he can demonstrate by a preponderance of the evidence that he reasonably believed that furnishing the

information would have resulted in a severely adverse effect on the physical or mental health of the patient.

(5) A physician who complies with the provisions of this section may not be held civilly liable to his patient for failure to obtain informed consent under Section 78-14-5.

**History:** C. 1953, 76-7-305, enacted by L. 1974, ch. 33, § 5; 1993, ch. 70, § 2.

**Amendment Notes.** — The 1993 amendment, effective May 3, 1993, rewrote former

Subsection (2) as the present second sentence of Subsection (1) and added present Subsections (2) through (5).

### **76-7-305.5. Consent — Printed materials to be available to patient — Annual report of Department of Health.**

(1) In order to insure that the consent to an abortion is truly informed consent, the Department of Health shall publish printed materials, and make those materials available at no cost to any person upon request. The material shall be easily comprehended and shall contain all of the following:

(a) geographically indexed materials designed to inform the woman of public and private services and agencies available to assist her through pregnancy, at childbirth, and while the child is dependent. Those materials shall contain a description of available adoption services, including a comprehensive list of the names, addresses, and telephone numbers of public and private agencies that provide those services, and explanations of possible available financial aid. The information regarding adoption services shall include the fact that private adoption is legal, and that the law permits adoptive parents to pay the costs of prenatal care, childbirth, and neonatal care. The department may, at its option, include printed materials that describe the availability of a toll-free 24-hour telephone number that may be called in order to obtain, orally, the list and description of services and agencies in the locality of the caller;

(b) descriptions of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from fertilization to full term, accompanied by pictures representing the development of an unborn child at those gestational increments. The descriptions shall include information about brain and heart function and the presence of external members and internal organs during the applicable stages of development. Any pictures used shall contain the dimensions of the fetus and shall be realistic and appropriate for that woman's stage of pregnancy. The materials shall be objective, nonjudgmental, and designed to convey only accurate scientific information about an unborn child at the various gestational ages;

(c) objective descriptions of abortion procedures used in current medical practice at the various stages of growth of the unborn child, the medical risks commonly associated with each procedure, including those related to subsequent childbearing, the possible detrimental psychological effects of abortion, and the medical risks associated with carrying a child to term;

(d) any relevant information on the possibility of an unborn child's survival at the two-week gestational increments described in Subsection (b);

(e) information on the availability of medical assistance benefits for prenatal care, childbirth, and neonatal care;

(f) a statement conveying that it is unlawful for any person to coerce a woman to undergo an abortion;

(g) a statement conveying that any physician who performs an abortion without obtaining the woman's informed consent or without according her a private medical consultation may be liable to her for damages in a civil action at law; and

(h) information regarding the legal responsibility of the father to assist in child support, even in instances where he has agreed to pay for an abortion, including a description of the services available through the Office of Recovery Services within the Department of Human Services, to establish and collect that support.

(2) The material described in Subsection (1) shall be printed in a typeface large enough to be clearly legible.

(3) Every facility in which abortions are performed shall immediately provide the informed consent materials described in Subsection (1) to any patient or potential patient, upon her request.

(4) Prior to the performance of the abortion every facility in which abortions are performed shall notify each patient who seeks an abortion that the informed consent materials described in Subsection (1) are available. This subsection does not apply if the patient's attending or referring physician certifies in writing that he reasonably believes that provision of the materials to that patient would result in a severely adverse effect on her physical or mental health.

(5) The Department of Health shall compile and report the following information annually, preserving physician and patient anonymity:

(a) the total amount of informed consent material described in Subsection (1) that was distributed;

(b) the number of women who obtained abortions in this state without receiving those materials;

(c) the number of statements signed by attending physicians certifying to his opinion regarding adverse effects on the patient under Subsection (4); and

(d) any other information pertaining to protecting the informed consent of women seeking abortions.

**History:** C. 1953, 76-7-305.5, enacted by L. 1981, ch. 61, § 1; 1982, ch. 18, § 1; 1985, ch. 42, § 1; 1993, ch. 70, § 3.

**Amendment Notes.** — The 1993 amend-

ment, effective May 3, 1993, rewrote this section, adding the last two sentences of Subsections (1)(a) and (1)(b) and adding Subsections (1)(d) through (e) and Subsection (2).

### **76-7-307. Medical procedure required to save life of unborn child.**

If an abortion is performed when the unborn child is sufficiently developed to have any reasonable possibility of survival outside its mother's womb, the medical procedure used must be that which, in the best medical judgment of the physician will give the unborn child the best chance of survival. No medical procedure designed to kill or injure that unborn child may be used unless necessary, in the opinion of the woman's physician, to prevent grave damage to her medical health.